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Regulation of the Importation, Interstate Movement, and Intrastate Movement of Plant Pests

Final Environmental Impact Statement—May 2018

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Environmental Impact Statement—May 2018

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Executive Summary

The provisions of the Plant Protection Act of 2000 (Title IV of Pub.L.106–224 (PPA)) at section 412(a) (codified at 7 United States Code (U.S.C.) § 7712) enhanced the ability of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) to safeguard American agriculture and the environment by expanding the range of organisms permitted for movement to include biological control organisms and associated articles. The current regulations (codified at 7 Code of Federal Regulations (CFR) part 330) lack transparency when describing regulations for biological containment facilities, the hand-carry authorization, and packaging and labeling requirements which affect risk-based permitting decisions. Revisions to the current permitting regulations for movement of plant pests and associated articles have been under consideration since the advanced notice of proposed rulemaking (ANPR) published on Friday, September 27, 1996 (61 Federal Register (FR) 50767–50770, Docket No. 95–095–1). The revisions now being considered by APHIS are designed to provide consistency with the PPA.

The unregulated movement of plant pests and certain commodities containing plant pests into or within the United States poses an ongoing threat from the introduction of harmful invasive plant pests, diseases, noxious weeds, and the associated damage to agriculture and the environment. Historically, regulation could have precluded many pests from entering the country. The regulation of the movement of plant pests under 7 CFR part 330 provides protection against many organisms and their impacts. Indirect or unforeseen effects were overlooked by some applicants and some researchers prior to regulation. Effective permit regulations need to include conditions to preclude potential adverse environmental impacts, as well as risks from pathogen and pest species.

The regulatory decision related to an application for the movement of a plant pest or an associated article ranges from a denial of the application to an issuance of a permit with mitigating conditions. Permits are time-limited and have an expiration date; currently, requests for amendment or reissue are considered on a case-by-case basis. Permits for movement into the environment in the United States are issued with the understanding that the organism being released may become established and spread to its maximum geographic range based upon host distribution. The information required of the permit applicant is critical to an informed decision by APHIS–Plant Protection and Quarantine (PPQ), Pest Pathogen and Biocontrol Permits, and Containment, Soil, and Federal Noxious Weeds, referred to collectively as the Pest Permit Branch (PPB). Potential pest risk and indirect environmental impacts are evaluated prior to authorizing movement of any organisms.

This environmental impact statement (EIS) addresses the potential environmental impacts associated with the regulatory changes under consideration and other alternatives. The three alternatives considered in this EIS include no action, the proposed revision of 7 CFR part 330 regulations, and a comprehensive risk mitigation program. There are potential environmental consequences associated with each of these alternatives. The no action alternative involves the ongoing permitting process under the current 7 CFR part 330 regulations. This alternative does not incorporate recent policy decisions, the experience of permit analysts, or more efficient permitting processes—it serves as a baseline for comparison of the alternatives. The proposed revisions are part of an ongoing effort to ensure that the basis for agency decisions is science-based, efficient, transparent, and adequate for mitigation of potential environmental and plant pest risks by increased consistency with the PPA. The comprehensive risk mitigation program alternative offers a broad risk mitigation strategy, extensive monitoring, increased compliance efforts, and additional provisions to remediate unforeseen impacts. It requires the largest staffing, most extensive regulatory infrastructure, and the greatest fiscal resources to administer.

The agency decisions to permit movement or release of an organism are based on considerable information about the potential pest and environmental risks. As a document reviewing the permit process, this EIS comprehensively reviews potential impacts to the environment from permitting decisions overall. This EIS finds that analysis of the application information under the proposed revisions sufficiently informs agency decisions about appropriate permit conditions to preclude adverse environmental impacts.

Regulatory decisions regarding the movement of biological control organisms, noxious weeds, and plant pests are made based upon their potential plant pest risk. Potential plant pest risks are determined on a case-by-case basis for each permit application under the current regulations. However, prior enabling authority did not extend explicitly to entomophagous (insect-feeding) biological control agents. Pursuant to our authority granted by the PPA, the proposed rulemaking establishes permitting requirements for the importation, interstate movement, and environmental release of most biological control organisms. It does, however, allow an exception from such permitting requirements for interstate movement and environmental release of certain biological control organisms that have become established throughout their geographical range within the continental United States such that additional releases of pure cultures of these organisms into the environment will result in no significant impacts on plants, plant products, or any other aspect of the human environment.

Regulatory decisions regarding biological control organisms depend upon agency review of information related to establishment and pest risk status. This approach provides a streamlined review and decision process with guidelines that are more transparent to the permit applicant. The comprehensive risk mitigation program differs by invoking a lower risk tolerance in the analysis.

Many plant pests routinely requested to be imported or moved interstate pose a lack of, or negligible, risks to agriculture and the human environment. Few of these organisms create adverse environmental or unanticipated pest or pathogenic impacts when moved or released into the environment. Under the proposed revisions, the interstate movement of certain plant pests could be explicitly granted an exception or exemption from permitting requirements. Novel permit applications would still be subject to in-depth review. The comprehensive risk mitigation program would require unequivocal information about all uncertainties and unknowns related to pest risk. This approach provides the most complete evidence of protection against pest and environmental risks, but does not definitively rule out all uncertainties and unknowns when an organism is first released into a new environment. Under this alternative, the time required to reach a permitting decision is likely to be much greater than decisions under the other alternatives.

The current regulations for means of transport, packaging, and labeling of the regulated organisms are subject to considerable interpretation. Although this provides regulatory flexibility, it also increases the potential for unintentional release of plant pests. To reduce the chance of accidental release, the proposed revisions codify the means of transport, packaging, and labeling requirements to prevent confusion over appropriate mitigation of risks during movement. These requirements do not apply to organisms exempt or excepted from the need for a permit.

The level of required containment of plant pests varies under each of the alternatives. The current regulations require facilities to be "adequate," but do not define containment criteria. The proposed revisions require all sites and facilities to be available for inspection, and prevent the dissemination or dispersal of plant pests, biological control organisms, or associated articles. The comprehensive risk mitigation program alternative would include expanded criteria, including extensive inspection, monitoring, and disposal requirements.

Contamination of organisms to be moved is a critical issue in mitigating potential pest risk. The current regulations accept the purity of organisms to be moved from statements of the applicant unless there is evidence to the contrary. The comprehensive risk mitigation program would establish

rigorous standards and a certification process to ensure that all organisms to be moved are not contaminated.

Uncertainties related to the extent to which organisms may adapt to their surroundings and respond to environmental conditions upon release are an ongoing issue for each of the alternatives considered in this EIS. Permit review processes are rigorous, yet provide enough flexibility to accommodate adequately justified and researched permit applications. Decisions for containment or movement into the environment are based on scientific information demonstrating a consistent pattern of response of target host plants and related plants. Contained studies generally provide evidence for the nature of response of the organism to survive; however, there remains no logistical way to test all unique conditions to which the organism will be exposed upon release. The ability to safeguard American agriculture, plant resources, and ecosystems is enhanced under the proposed alternative.

Permitting decisions based on pest risk potential may not transparently document considerations of potential cumulative effects, indirect effects, and effects from adaptation of the organisms; however, agency decisions, overall, are anticipated to reduce risk and produce beneficial outcomes. The review process considers both the present permit application and impacts from prior permits to understand the potential cumulative effects. Releases of similar species or species with the same or closely related hosts are examined comparably. The current agency requirements to review each application on a case-by-case basis ensure decisions are based on the best available scientific information. Unforeseen impacts are limited to effects resulting from issues of uncertainty and unanticipated results. Under the proposed regulations and comprehensive risk mitigation program, the analyses that support exceptions from permitting would be more transparent and avoid case-by-case redundancy of effort. The proposed regulation provides rapid mechanisms to mitigate risk associated with organisms when circumstances change.

The proposed revision includes reasonable measures to preclude and mitigate likely and foreseeable impacts resulting from permits issued for the movement of plant pests, including biological control organisms and soil. The need for a comprehensive risk mitigation program is not considered justified at this time because there appears to be adequate protection of plant resources in the proposed revision. Ongoing review of the permitting process may suggest the need to revisit this issue or certain aspects of an expanded permitting process. Ongoing review may also lead to further revisions in criteria for permit regulations on the movement and release of plant pests to the environment in the future.

I. Purpose and Need

The U.S. Department of Agriculture (USDA)–Animal and Plant Health Inspection Service (APHIS)–Plant Protection and Quarantine (PPQ) is proposing to revise the 7 Code of Federal Regulations (CFR) part 330 regulations regarding the movement of plant pests, soil, biological control organisms, and associated articles for the purpose of consistency with the Plant Protection Act of 2000 (PPA) (Title IV of Pub.L.106–224 (PPA)) at section 412(a) (codified at 7 United States Code (U.S.C.) § 7712). This environmental impact statement (EIS) is prepared to provide the decisionmaker with analyses of potential environmental impacts of different alternatives to make an informed decision. This chapter of the document provides the background and the basis for the action being proposed by APHIS, including—

- a section on history of biological control and the PPQ Pest Permitting Branch (PPB) (currently comprised of the Pest Pathogen and Biocontrol Permits group, and the Containment, Soil, and Federal Noxious Weeds group) to assist the reader in understanding the context for the proposed changes;
- the purpose and need for regulatory changes;
- background about scoping and the issues of focus related to various permit application decisions; and
- an explanation of the relationship of the permit process analysis within this documentation to permit-specific environmental assessments (EAs) prepared for individual permit applications.

The broad analysis of common elements within the permit process provides a basis for analyzing the effectiveness of different alternatives and methods for managing the potential environmental risks from permit decisions. This chapter provides a context for the later chapters regarding alternatives and environmental consequences.

A. Introduction

The PPB is responsible for the review and issuance of permits for the movement of plant pests and soil. With the ongoing submissions of permit applications to move plant pests, soil, biological control organisms, noxious weeds, and associated articles, concern continues to be expressed over the threat of introduction and dissemination of harmful pathogenic and pest species. There is concern that the permit process needs to provide a timely mechanism for movement of low risk species that may result in positive impacts. The introduction provides some historical

information about past practices and regulation of plant pests and biological control organisms to assist in the understanding of the permitting issues that must be analyzed to manage the positive impacts and risks.

1. History of Plant Pest Permitting

Under the Federal Plant Pest Act of 1957 (FPPA), USDA was provided explicit statutory authority to issue permits for the movement of plant pests into and through the United States. This authority was updated and expanded in the PPA. Under the PPA, a plant pest is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: a protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of those articles, including unidentified organisms associated with infected plant parts. In the PPA, the definition was expanded from invertebrate animals to include all nonhuman animals; however, other than this change, the definition is identical to that provided in the FPPA. The intent of both Acts is to prevent the entry and dissemination of organisms that could, directly or indirectly, adversely affect the plant resources of the United States. Permits allow living plant pests that would otherwise be prohibited from movement into or through the United States to be so moved when authorized by a PPQ permit. Permits are issued only when sufficient safeguards are in place to prevent the escape or dissemination of plant pests, and the organisms do not present an unacceptable level of risk to American agriculture and natural resources.

When permitting regulations were first established by APHIS during the 1970s under the FPPA, they supported what was construed as a small research community, based on the volume of permits, occupations of applicants, and range of permitted organisms. Typically, the applicants' needs were met by individuals mailing plant pests under PPQ permit from foreign sources, and from other States to their laboratories. The intent of these movements was to provide for genetic diversity within their research, and enhance the discovery and use of new species. In the majority of cases, the imported organisms were not intended for direct release into the environment or for direct viewing by the public (e.g., butterfly houses and zoos). Importations and interstate movements were of small volumes of live pests with limited direct commercial value. It was expected that individual researchers had a vested interest in keeping pure cultures of pest populations under strict control within their laboratories.

While importation and interstate movement of live pests, based on permit condition restrictions, worked well for the research community since the regulations in 7 CFR part 330 §§ 200–212 were established, additional applications for movement for other intended uses require different

conditions to mitigate pest risk. These permit applications include organisms imported for use as fish bait; import and interstate movement of various invertebrates (e.g., snails, walking sticks, and cockroaches) for the pet trade; the import of exotic butterflies, moths, and other invertebrates for educational display; the import and interstate movement of infected or infested plant materials for diagnostic purposes; and the interstate movement of native butterflies for release at weddings and other celebrations. With expanded availabilities and efficiencies of commercial overnight delivery services, the ability of nearly any interested U.S. resident to rapidly obtain living organisms from nearly any part of the world resulted in increasing numbers of more complex organism permit applications. Additionally, the number of commercial entities conducting biological research dramatically increased.

Accordingly, the numbers of applications, issued permits, and containment facility inspections have increased dramatically over the last 15–20 years. For example, the number of inspected containment facilities increased from fewer than 125 facilities to approximately 3,100 over the past decade. Two scientists and two support staff handled all the live pest applications in the early 1990s; now there are 15 senior and staff scientists, with a need to further increase staffing levels to keep pace with increasingly complex applications. Three (or a functional equivalent of 3) of the 15 scientists involve containment evaluation positions to coordinate facility inspections with APHIS field personnel. The position of permit compliance officer was added to serve as a liaison during the processing and coordination of the PPB's response during any APHIS Investigative Enforcement Service review of violations of permit conditions. In addition, receipt and review of applications, data entry, and the issuance of permits and shipping labels now require additional support staff.

2. History of Biological Control Permitting

Historically, the movement and environmental release of organisms intended for the biological control of invertebrate plant pests (insects, mites, and nematodes), microbial plant pests, and noxious weeds were regulated under PPQ permit. Although the risk of direct and indirect impacts on nontarget plants have always justified the establishment of permit conditions for movement of biological control organisms, the associated outcomes of such movement are anticipated to result in positive impacts to agriculture. A major addition to USDA's statutory authority to regulate organisms intended to control plant pests and weeds was included in the PPA. The PPA also includes a statement that the movement of enterable organisms, including those for biological control, is vital to the U.S. economy and should be facilitated to the extent possible. Prior to the PPA, a legal definition of a biological control organism was not present in the statutes of the United States, and APHIS regulated them under statutes and regulations pertaining to plant pests. Although many biological control organisms may have plant pest characteristics, this approach

created much confusion and concern within the biological control community.

Biological control organisms are now defined as any enemy, antagonist, or competitor used to control a plant pest or noxious weed. The implications of this definition have yet to be incorporated into the APHIS regulations; therefore, biological control organisms continue to be regulated under the existing plant pest regulations.

When intended to control weeds, biological control organisms fit well within the legal definition of a plant pest permits for environmental release of these organisms are only issued when scientific information is presented to show they are sufficiently specific to their weedy host plants, and adverse impacts are not expected to occur. This information is presented to the public for comment prior to issuance of the permit for initial environmental release in the form of an EA under the National Environmental Policy Act of 1969 (NEPA), (42 United States Code (U.S.C.) 4321 et seq.) and the associated APHIS implementing regulations (7 CFR part 372). The process also requires considerations of impacts to threatened and endangered species under the Endangered Species Act (ESA) (16 U.S.C. § 1531 et seq.). Even when a finding of no significant impact is found under NEPA, and a permit is issued for the first-time release of a weed biological control organism, permits are required for all subsequent importations and interstate movements of the organism.

The regulation of biological control organisms intended to control invertebrate and microbial plant pests is a more complex and sometimes controversial issue. Although the intended use of these biological control organisms is to decrease the adverse impacts of pests on plants, they may be associated with their pestiferous hosts during movement. They may have nontarget impacts on native species and/or threatened and endangered species. In addition, some of these organisms may indirectly cause adverse impacts on plants by attacking unintended beneficial organisms, such as those that otherwise control weeds or other plant pests. Consequently, a plant pest permit is required for their importation. Under policies and procedures adopted during 2001, following an agreement among Canada, Mexico, and the United States under the North American Plant Protection Organization (NAPPO), when an entomophagous (insect-feeding) biological control organism not indigenous to North America is imported into a containment facility, the researcher must subsequently apply for a permit for environmental release. When information is supplied with the application that indicates adverse plant or environmental impacts are unlikely to occur, the PPB determines the organism not to be a plant pest and no subsequent plant pest permit is required for its interstate movement and environmental release. Under this process of determining no jurisdiction, no NEPA document (i.e., EA) is

produced to inform the public as to how the decision was made. However, a permit is always required for the movement of these biological control organisms when accompanied by their pestiferous hosts, even when established in the United States. APHIS regulates interstate movement and environmental release of these organisms; however, the current regulations do not reflect this activity.

3. Efforts to Update APHIS–Plant Pest Permitting Regulations

In the early 1990s, APHIS recognized the need to modify the existing plant pest permitting regulations to more explicitly define the requirements for the movement and environmental release of biological control and other organisms. With input from the newly established APHIS National Biological Control Institute (NBCI), the agency began developing amendments to the existing regulations focused primarily on invertebrate and microbial organisms used to biologically control plant pests. This effort was stimulated by a controversial application by a USDA–Agricultural Research Service (ARS) scientist to release a nonindigenous biological control organism against native grasshoppers. The agent was not specific to pest grasshoppers and threatened to disrupt existing natural controls of native weedy plants by other native grasshopper species. APHIS' denial of this permit application caused much controversy within the biological control community, which highlighted the need for APHIS to either clarify existing regulations or develop new regulations for biological control organisms. Consequently, APHIS began moving forward with new regulations to cover these situations. The existing plant pest permitting regulations were considered adequate for organisms intended for the biological control of weeds.

During the late 1980s and early 1990s, there was increasing recognition by the scientific and regulatory communities of the adverse environmental and economic impacts to the United States caused by many nonindigenous organisms. Due to these concerns, Congress directed the Office of Technology Assessment (OTA) to develop a report on nonindigenous species which they published in 1993 (OTA, 1993). This report identified not only nonindigenous plant pests and weeds as major problems, but also certain biological control organisms, especially some vertebrate biological control agents released during the early 1900s. The overwhelming acceptance of this report by the scientific and regulatory communities prompted APHIS' Administrator's Office to redirect the efforts of the group developing biological control regulations to develop a more expansive regulation to cover all nonindigenous organisms under APHIS' jurisdiction. Because biological control research often includes the introduction of nonindigenous organisms, this redirection appeared to be a logical outcome of the OTA report. APHIS subsequently published proposed nonindigenous species regulations in 1994, which included proposed requirements for all nonindigenous biological control organisms.

The proposed restrictions on the movement and release of nonindigenous organisms were expansive, and public comments were overwhelmingly negative, especially from the biological control community. A major problem was that the new regulation defined all biological control organisms as indirect plant pests, regardless of their actual or potential benefit to plants. Due to the overwhelming negative responses, APHIS withdrew the proposed rule in 1995. As part of the withdrawal, APHIS stated that the rule would have imposed unnecessary restrictions on the introduction of organisms. APHIS also proposed to publish an advanced notice of proposed rulemaking (ANPR) that would seek public comment on the controversial parts of the nonindigenous species proposed rule, especially those parts dealing with the working definition of direct and indirect plant pests as related to biological control organisms.

During 1995, NBCI made available for review a draft document entitled "Options for Changes in Biological Control Regulations and Guidelines in the United States: A Strawman for Comment." This document summarized suggestions and ideas collected by NBCI from experts, primarily in biological control, beginning in 1992. Although this document was never accepted as official APHIS policy, many of its elements were considered in subsequent regulatory endeavors. Ten main areas for improvement of biological control regulation were identified, including—

(1) modifications to the FPPA;

(2) notification of importation from non-U.S. sources of biological control agents, and for interstate movement of precedented and unprecedented agents;

(3) approval of facilities into which agents are imported from overseas or moved interstate;

(4) notification for field release into the environment of precedented agents;

(5) clarification of procedures required for commercial use of agents;

(6) implementation of a two-tiered system for evaluation of risks for release of unprecedented agents;

(7) exclusions from regulatory oversight;

(8) resolution of conflicts of interest;

(9) developing a new statute that would enable and protect biological control; and

(10) increased customer service.

In 1996, APHIS published an ANPR that primarily sought public comment on how to interpret indirect plant pest risk, and also sought input on other important aspects of regulatory reforms, including criteria to help define what constitutes a plant pest, the use of voluntary standards, and environmental release criteria. It also recognized the merits of other ongoing attempts to prompt regulatory reforms. In the ANPR, APHIS proposed that an indirect plant pest was one that did not directly feed upon, infest, or cause damage to plants, but indirectly affected other organisms so that the beneficial or protective effects of these organisms on desirable plants were compromised. For example, a wasp (i.e., hyperparasite) that parasitizes another species of wasp that attacks a direct plant pest is considered an indirect plant pest because its impacts through the food chain are negative to the productivity or survival of the desirable plant. The wasp that parasitizes the direct plant pest is not considered to be a plant pest because it ultimately has a beneficial impact on the plant. However, if the plant were a weed (i.e., adversely impact desirable plants), then the hyperparasitic wasp would be an indirect plant pest. Unlike the previous proposed rule, this definition implied that even though a species is nonindigenous, it may not be a plant pest. This proposal and others in the ANPR resulted in mostly positive public comments.

Following the ANPR, a USDA interagency workshop was organized by APHIS in October 1996, at the request of the Deputy Secretary of Agriculture, to seek stakeholder guidance and to provide the Department with advice on, among other topics, regulation of biological control organisms. The workshop included USDA representatives from APHIS, ARS, the Cooperative State Research, Education and Extension Service (CSREES, now known as the National Institute of Food and Agriculture), and the U.S. Forest Service (FS), as well as State departments of agriculture and land grant universities. Several regulatory or procedural recommendations resulted from the workshop, including the following—

- provide consistency between regulatory requirements and actual risks to nontarget organisms and the environment;

- assess benefits associated with any action in addition to the potential risks;

- develop processes and assessments that are science-based;

- develop processes that are streamlined, consistent, predictable, and efficient;

- provide "one-stop" shopping for regulatory compliance, including efficient access to information; and

- develop a "facilitative regulatory system."

In response to the workshop, APHIS formed the Biological Control Coordinating Council in 1996. It was composed of the four USDA agencies present at the workshop and was charged, in part, with advising APHIS in its organism regulatory reforms process, specifically those affecting biological control. A new draft proposed rule was developed during 1998, but considerable internal USDA reviews and suggested modifications delayed the submission of the proposed rule for publication. The delays generally concerned provisions in the draft proposed rule related to the regulatory oversight of biological control organisms. The Biological Control Coordinating Council recommended various changes to the draft to be more facilitative to biological control endeavors. Among the proposed changes was a request to remove the permitting requirements for the interstate movement of previously released biological control organisms of weeds, and procedures for establishing lists of precedented organisms requiring little or no further regulation. Deregulation of these organisms was incorporated into the draft proposed rule, as well as several other recommendations from the Biological Control Coordinating Council.

The draft proposed rule was submitted to the Office of Management and Budget (OMB) for review in 1999. Review of the proposed rule by other Federal agencies raised concerns about the blanket removal of previously released weed biological control organisms from permit requirements for interstate movement without individual assessments on environmental impacts. As a result of these concerns, OMB recommended that the proposed rule not be published with these provisions present. APHIS agreed to remove these sections from the proposed rule and place them in a separate ANPR for public comment. The revised proposed rule and the ANPR were presented to OMB during the spring of 2000. Upon passage of the PPA in June 2000, further review of the proposed rule was necessary, especially concerning the new provisions for biological control organisms. Internally, APHIS considered withdrawing the proposed rule from OMB review to incorporate the new authorizations of the PPA. Considering the length of time it took to develop the proposed rule, as well as the controversies these efforts generated, APHIS eventually decided to proceed with the publication of the existing proposed rule with only the new definitions from the PPA incorporated. A new proposed rule change was anticipated for the future that would more fully incorporate all the

provisions of the PPA. The proposed rule was published in the Federal Register (FR) on October 9, 2001.

APHIS received approximately 3,000 comments on the proposed rule. Most were from commercial enterprises, educators, and students concerned about provisions in the proposed regulation change which suggested that interstate movement and environmental release of native butterflies would be prohibited if this proposal was fully enacted. A simple rephrasing of a single sentence in the lengthy proposal would have corrected this misperception. Fewer than 200 comments were received from the scientific community, most of which were positive and constructive. The biological control community was largely supportive of the proposal.

The proposed rule was published just a few weeks after September 11, 2001, and comments were being received during the period when letters purposely contaminated with anthrax were detected in the U.S. postal system. These events caused a near-immediate examination of the APHIS pest permitting regulations, policies, procedures, and oversight as a possible pathway for bioterrorism. In 2002, the USDA–Office of the Inspector General (OIG) began an audit of pest permitting. The OIG audit report was published in 2003 and contained several recommendations for change. In general, OIG found that APHIS' pest permitting lacked appropriate regulatory procedures for such critical areas as enforcement of permit conditions, tracking of shipping labels authorizing importations, initial and follow-up inspections of containment facilities, tracking of organisms imported in personal baggage or automobiles (i.e., hand-carrying), and oversight of permits for diagnostic laboratories. Even while the OIG audit was underway, APHIS began modifying its policies and procedures. These changes continued following the publication of the audit report.

In 2003, most APHIS inspectors at ports of entry to the United States were transferred to the Customs and Border Patrol (CBP) in the newly created Department of Homeland Security. As a consequence of this change, new interagency procedures and communication lines were developed for clearing shipments of permitted organisms at ports of entry. The increased scrutiny of packages containing any living organisms by CBP resulted in processing and other delays for individuals who import biological organisms other than plant pests or biological control organisms. This increased the number of individuals requesting help from the PPB to clear their packages or to obtain official letters of no jurisdiction.

An internal APHIS review of organism permitting was completed in December 2005. Among the findings and recommendation of this review was the need to reinitiate the process of revising the organism-permitting

regulations. As a result, APHIS decided to withdraw the proposed rule published in 2001, and replace it with the current revised and updated proposal based on the previous proposed rule, the comments received on that proposed rule, new provisions in the PPA, other available information, and on the events and changes that occurred since 2001.

Simultaneous with the regulatory efforts, there was ongoing work to improve the efficiency of processing permit applications. USDA developed "ePermits" to provide a secure way for agency stakeholders to apply for and receive permits. This computer application software also allows other Federal and State entities to rapidly verify the authenticity and accuracy of import permits. From an APHIS perspective, ePermits replaced a paper-based office procedure and legacy computer software while simultaneously computerizing the essential State review and applicant-initializing steps that precede permit issuance.

Although planning for an ePermit system began in 2000, and the contract was awarded in 2002 to Science Applications International Corporation for its development, the software was implemented for PPQ permits in 2006 and has ongoing maintenance contracts. The system components consist of web services built with open-source code within a service-oriented architecture. This allows workflow changes to be made without code changes, and workflow is tracked for each permit.

B. Purpose and Need for Action

1. Purpose

APHIS is proposing to revise the regulations regarding the movement of plant pests, soil, biological control organisms, and associated articles for the purpose of consistency with the PPA. Although the PPB adjusted its internal protocols to include consideration of permits for biological control organisms, among other commodities, there has been no focused effort to promulgate rules addressing this movement. The PPB reviews applications for movement of plant pests, and accumulated considerable experience regarding plant pest risks associated with authorizing permits. This accumulated experience allowed the PPB's permit reviewers to refine their environmental and pest risk considerations to focus on specific criteria that pose greater potential risk. The knowledge gained from the extensive review of numerous permit applications served to refine the decision criteria and increase the certainty of anticipated outcomes for authorized movements and releases of plant pests and biological control organisms. Much of this ongoing review resulted in various internal policy decisions regarding permitting decisions not yet placed into regulations or subject to public input. It is important to APHIS that the potential changes in permitting practices resulting from the PPA and ongoing reviews be addressed through revisions to the current regulations in a manner that ensures a clear and informed basis for decisions. This

EIS serves to inform the decision about potential environmental impacts from alternative methods to accomplish the permitting process.

2. Need

The changes in the PPA make it necessary to harmonize regulations in 7 CFR part 330 for consistency. The changes ensure that the regulatory basis for agency decisions regarding permit applications for movement and releases of these organisms are clear to the applicants. Although the effective use of biological control organisms in eliminating plant pests from crops and other plants were always of concern to APHIS, the cooperative facilitation of this use is cited as an agency responsibility in the PPA. The manner of regulatory changes to cover these organisms, and plant pests associated with movement of commodities needs to ensure that the imports and interstate commerce in agricultural products and other commodities are facilitated to the extent practicable, while still reducing the risk of dissemination of plant pests. The clarification of the data that are the basis for the decisionmaking process for a given permit application make it easier for a permit applicant to determine what is needed by the PPB to expedite the process.

3. Authority to Take Action

APHIS' authority for action and cooperation with other agencies, in the movement and release of plant pests, is based on Title IV of the Agricultural Risk Protection Act of 2000—PPA, Public Law 106–224, 114 Stat. 438–455, which authorizes the Secretary of Agriculture to facilitate exports, imports, and interstate commerce in agricultural products and other commodities that pose a risk of harboring plant pests or noxious weeds in ways that will reduce, to the extent practicable, as determined by the Secretary of Agriculture, the risk of dissemination of plant pests or noxious weeds. This includes facilitation of the movement of biological control organisms in cooperation with other Federal agencies and States. In particular, sections 411 to 414 in Subtitle A of the PPA stipulate required regulations for movement of plant pests, biological control organisms, noxious weeds, and other associated articles. The current regulations for these sections of the PPA are found in 7 CFR part 330.

4. Statutory Authority

The documentation prepared in this EIS is designed specifically to address the requirements of NEPA, 42 U.S.C. 4321 et seq. It is prepared to comply with APHIS' NEPA Implementing Procedures (7 CFR part 372), USDA's NEPA Regulations (7 CFR part 1b, 3100), and the President's council on Environmental Quality (CEQ) NEPA Regulations (40 CFR part 1500 et seq.). To the extent that some importation actions affect foreign individuals and overseas companies, this EIS also fulfills the requirements of Executive Order 12114—Environmental Effects Abroad of Major Federal Actions.

C. Scope and Focus of This Environmental Impact Statement

The framework for decisionmaking at APHIS regarding the permit process for movement of plant pests and soil involves documentation for the consideration of individual requests by applicants for specific purposes. The documentation encompasses regulation of movement of phytophagous (plant-feeding) and entomophagous (insect-feeding) biological control organisms, soil, and other articles associated with plant pests covered in 7 CFR part 330. This EIS limits agency consideration to the ongoing and proposed changes to the permit process that have been developing over many years of experience and effective permit regulation.

Permit applications are received by the PPB and their disposition ranges from a denial to an issued permit. Applications may be denied for any of the reasons in 7 CFR § 330.204, and may include: (1) acceptable safeguards cannot be arranged, (2) the risk for destructive potential outweighs the proposed benefits, (3) past violator status or the applicant demonstrated an unwillingness or inability to meet permit conditions, (4) the pest's movement conflicts with an APHIS program, or (5) objections from a State. Issued permits may be revoked for similar cause. Applications may be denied in part, and can be withdrawn at the request of the applicant at any time. Issued permits may be amended upon request by the permit holder or without such a request when APHIS finds that circumstances have changed. Amendments to an issued permit are considered on a case-by-case basis. When a permit holder leaves an institution or dies, the PPB works to ensure the regulated organisms are either destroyed or a new permit is issued to a responsible party in a timely fashion. The permit conditions specify that any changes in the status of the permit holder or institution need to be reported to the PPB.

This section is organized to provide the reader with an understanding of PPB functions as they relate to the scope of this EIS. The first segment gives an overview of the public comments received during the scoping period. This is followed by segments describing PPB review of containment facilities, permitting decisions for contained organisms, permitting decisions for release of organisms into the environment, and permitting decisions for movement of soil. It should be recognized that the PPB permit analyst's review of an individual permit application will vary with the associated environmental and pest risks of concern. Some categories of permits (e.g., butterfly house permits and zoological display permits) in this section may share common regulatory and review requirements. Therefore, there is some repetition of information with common applicability to permitting of plant pests. This order of presentation serves to assist the reader and applicants in understanding the permit review process for specific applications submitted to the PPB. The

permit analyst's review of an individual permit application may indicate the need for consideration of other issues.

1. Public Comments

On Tuesday, October 20, 2009, APHIS published a notice of intent in the FR to prepare an EIS for the movement of plant pests, biological control organisms, and associated articles (Docket No. APHIS-2008–0076, 10/20/2009, V. 74, No. 201, p. 53673–53674). That notice identified three broad alternatives to consider in this EIS, and requested public comments to help delineate the scope of the issues and alternatives to be analyzed. The 30-day period for scoping of public comments was extended to Thursday, November 19. (This FR notice is provided in appendix E of this EIS.)

There were 14 public comments received within the scoping period for this EIS. The respondents included the National Institute of Food and Agriculture (USDA), two State departments of Agriculture, four University professors engaged in research on biological control organisms, two biological control organizations for producers and researchers, one registrant for biological control organisms as pesticides, one advocacy group for conservation of arthropod species, one organization for plant pathogen researchers, and two private citizens. The primary issues of concern expressed in the comments related to the selection of alternatives, adoption of specific mitigation measures, logistic considerations, harmonization of regulations with other agencies and other APHIS regulations, and issues related to regulation of biological control organisms. Although some comments related more to the rulemaking process than to the environmental consequences, this EIS addresses most of the concerns by including some agency logic for the selection of certain approaches taken to manage potential plant pest risks. APHIS was aware of most of the issues of concern to the respondents.

Based upon the public input received and review of the permit process, the scope of this document focuses on the regulatory basis for containment facility requirements and permitting decisions for movement of organisms and soil. The proposed amendments are restricted to 7 CFR part 330, so that other parts of the PPQ permit regulations (e.g., those permits for noxious weeds in 7 CFR part 360, and organisms regulated under 7 CFR 340) are neither considered nor analyzed in this EIS. (See the review process for containment below, and the description in chapter 2 for information about containment requirements. The environmental consequences of different alternatives to preclude pest and pathogen risks from these organisms, parts, or soil are provided in chapter 4.)

On January 19, 2017, APHIS published the proposed rule and draft EIS in the Federal Register (82 FR 6980–7004, January 19, 2017) for a 60-day comment period, and the Environmental Protection Agency published the

notice of availability of the draft EIS in the Federal Register on January 23, 2017 (82 FR 7822, January 23, 2017). APHIS notified the public of the proposed rule and draft EIS on its stakeholder registry, and notification letters were sent to those in the distribution list in appendix C of this EIS. APHIS extended the comment period for another 30 days on February 13, 2017 (82 FR 10444, February 13, 2017). (These FR notices are provided in appendix E of this EIS.) A total of 60 comments were received on the proposed rule and draft EIS. The main issues regarding the EIS were regarding microbial pesticides, and strengthening the discussion of Executive Orders 13175 (Tribal consultation and coordination) and 12898 (environmental justice). Appendix G provides a summary of APHIS' response to these comments, and how APHIS addressed the concerns in the final EIS.

2. Biocontainment Facility Requirements

When permit applications include organisms that pose a potential risk to agriculture, APHIS requires containment of the regulated organism. Containment of regulated organisms may be accomplished by a combination of proper handling of the regulated organisms, and by physical and security attributes of the premises where the regulated organisms will be held. PPB containment specialists can determine the adequacy of a facility either by a computer-assisted facility evaluation (CAFÉ) or by a full inspection which includes an on-site inspection of the facility. The criteria used to determine the kind of evaluation needed (CAFÉ or full) before permit issuance is described in APHIS' web pages at: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/sa_containment/ct_containment_facility_inspections.

To determine if a facility's containment capabilities are adequate, all facilities may be inspected prior to approval of a permit. Consequently, the demand for inspections steadily increased to the point where available personnel and costs made this approach no longer feasible. As a result, APHIS regularly trains personnel to perform facility inspections; facility inspections are done by the trained employees during periodic site visits. This saved the Agency considerable expense and promotes compliance by allowing biocontainment facilities to be inspected at any time during normal business hours. The original purpose for developing the CAFÉ was for the prioritization of workload and for improved resource utilization. Initial on-site inspections of facilities serve as the baseline for the focus and improvements in subsequent inspections.

The individual reviews and inspections of biocontainment facilities are based on the dissemination potential and pest risk associated with the requested organism. If the PPB determines that containment is required, then an initial questionnaire is sent to the applicant via email or within the APHIS electronic permitting system (ePermits). The questionnaire

typically asks for floor plans, standard operating procedures, availability of certified key equipment, copies of certifications, photographs of key facility features (biosafety cabinets, autoclaves, nematode/seed traps, doors and windows, etc.), and related biosecurity information.

A PPB containment specialist evaluates the documentation provided by the applicant. Among the requested organisms, the one posing the highest risk determines the needed level of containment. If the requested organism is determined to have low to no dissemination potential and poses a lower pest risk to agriculture in the specific State/region, then the permitting process can continue if the PPB containment specialist finds the facility and handling procedures to be adequate for containment without an on-site facility inspection by APHIS officials. Permits issued by this process are designated as CAFÉ-processed permits.

If an organism poses higher potential risk to agriculture (e.g., imports from foreign sources), then a full inspection will be done before a permit is issued. In these cases, in addition to requiring initial information from the applicant, APHIS requires an on-site inspection of the facility. An inspection questionnaire in the APHIS electronic permitting system is sent to the PPQ State Plant Health Director (SPHD), and the SPHD assigns an APHIS official to conduct an inspection and complete the questionnaire. A permit is not processed until an on-site inspection is completed by an APHIS official, and the inspection report is evaluated by a PPB containment specialist. A permit is issued only after the facility is found to provide adequate containment based on an evaluation of the inspection report. Guidelines for containment of different plant pests and pathogens are available at: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/sa_containment/ct_containment_facility_inspections.

3. Permitting Decisions for Contained Organisms

The decision to issue or deny a permit is based upon many environmental and pest risk factors. This section discusses the primary factors considered by the PPB permit analyst in their review of a permit application to move an organism into a biocontainment facility. This section discusses only the most frequent types of organism requests.

a. Zoological Permits

(1) Educational Use Permits for Mollusks

The PPB issues interstate movement permits to educators who want to use various mollusk species (snails and slugs) in their classrooms. In 2003, the PPB conducted a survey of all States to develop a list of 10 mollusk species that could be authorized for educational use in classrooms. Each State's decision was based on the presence or absence of the mollusk in

their State. The decisions of the States (updated periodically) are presented on APHIS' web site in the form of a table (see https://www.aphis.usda.gov/plant_health/permits/downloads/snail_matrix.pdf). All permit authorizations for educational use are based on this Mollusk Decision Matrix. One snail in this table, *Cornu aspersum* (=*Helix aspersa*) originally from Europe, is a serious agricultural pest in virtually all agricultural settings. The States of Arizona, California, New Mexico, Texas, and Washington are the only States that would agree to the use of *Cornu aspersum*, the brown garden snail, in the classroom because this snail is already established in their respective States. The other species on the list are mollusks that are native to their respective States. Permit conditions specify that the organisms must be kept in locked containers and cannot be removed from the classroom.

(2) Zoological Display Permits

Permits are issued for zoos, museums, nature centers, and other institutions to display/exhibit domestic and exotic regulated arthropods for public education. (Butterfly house permits are discussed in the next section and involve certain unique issues related to containment.) Species selected for exhibit are generally tropical, large, colorful, slower moving, require a relatively long generation time and, therefore, the risk to agriculture and the environment is low to moderate for this category of plant pest. These organisms must be housed in escape-proof displays. To determine the adequacy of the display, biocontainment facilities are required for all imported exotic arthropods. A successful biocontainment facility evaluation report must be on file within the APHIS electronic permitting system folder prior to the consideration of a permit application. For selected low-risk exotic arthropods that are established within the United States, and domestic arthropods known to pose low risk, an evaluation report (CAFÉ) is sufficient.

Many factors are considered when evaluating permit applications for exhibiting arthropods. These include, but are not limited to, the natural range of the pest, distribution and abundance within this natural range, biology (reproductive capacity, overwintering, host range, diseases vectored, etc.), life stages being transported, whether the pest has any undesirable subspecies, endangered species considerations, and other factors. Foreign suppliers often provide details on the biology of the organism. To make the permitting decision, many sources are consulted including previous permits, letters of denials, and published and online resources.

In addition to biocontainment facility requirements, permit conditions may require specific cage designs, employee staffing requirements, and waste

disposal treatments. Regulated organisms cannot be redistributed intrastate or interstate except as authorized in the permit.

Records are required to be kept of all regulated organisms received for zoological display within a calendar year, and are provided to the PPB upon request. If requested, special arrangements can be made to use select species for outreach or offsite education. These permits limit the number of organisms that can be transported, who can carry these organisms, the type of packaging (able to resist a vehicle accident), and return of the organisms with substrate to the biocontainment facility.

(3) Butterfly House Permits

Permits are issued to zoos, museums, botanical gardens, and other public and private business for display/exhibit of domestic and exotic butterflies and moths (Lepidoptera) for public education. These exhibits present free-flying butterflies and moths, generally in a tropical rainforest setting where the visitor can walk among these species. Lepidoptera selected for exhibit are generally tropical and never include known agricultural pests. The risk to agriculture and the environment is low to moderate for these preselected plant pests. These organisms must be housed in an adequate biocontainment facility. A successful facility evaluation report must be on file within the APHIS electronic permitting system folder prior to the consideration of the application.

Many factors are considered when evaluating applications for exhibiting Lepidoptera. The most important factor is host plant range, both known and anticipated. Other factors include natural geographic range, dispersion and abundance in that range, biology (reproductive capacity, overwintering, parasitoids, etc.), whether the pest has any undesirable subspecies, interactions with endangered species, and other factors. Foreign suppliers often provide details on the biology of the Lepidoptera to the PPB permit analyst during the early stages of evaluating new species. Many sources are consulted in determining permit conditions, including previous permitting history, and published and online resources, such as—http://www.nic.funet.fi/pub/sci/bio/life/warp/lepidoptera-index-a.html; http://www.nhm.ac.uk/research-curation/research/projects/hostplants/; and http://www.butterfliesandmoths.org/.

Permit conditions for exhibiting Lepidoptera require some unique biocontainment facility features. First, the pupae must be housed in a special cabinet prior to emergence to prevent the escape of any possible parasitoids that emerge from these pupae; this allows for the collection and destruction of these parasitoids. Secondly, entrance and exits must provide a vestibule of at least 10 feet in length with self-closing doors on both ends to prevent escape of the moths and butterflies. Permit conditions may require employees to staff exit vestibules when visitors are present, and

include waste disposal management plans for all materials exposed to the regulated Lepidoptera. Known host plants for exhibited Lepidoptera are not allowed in the exhibit space. Only pupae can be imported. Regulated organisms cannot be redistributed in or out of State except as authorized in the permit. Annual records of all regulated Lepidoptera received typically are submitted each January to the PPB. Records must include the number of each species received from each supplier, and the final disposition for each pupa including whether it produced a successful specimen, died from disease, or produced parasitoids.

(4) Permits for Biological Supply Companies

The PPB issues interstate movement permits for regulated organisms sold by commercial suppliers. These organisms are primarily sold for use in school classrooms, but they also can be sold to private individuals. These permits are issued on a State-by-State basis to the supplier to distribute to the specified destination State. For these permits, the ultimate receiver does not obtain a permit. Most organisms offered in biological supply company catalogues are not agricultural pests. The few organisms that are known to be plant pests have specific conditions as a term of sale. APHIS discourages release of organisms purchased from these supply companies.

To reduce the likelihood of release, the PPB requires the supply company to provide the customer with a letter that explains how to dispose of the organisms that remain alive at the conclusion of their needs. The letter reinforces permit conditions that stipulate these organisms should not be released to the environment or given to students. Products sold by the weed biological control supply companies involve releases and are discussed in this chapter in section C.4, Permitting Decisions for Release Permits.

b. Biological Control Organism Permits

Permits for biological control organisms include arthropods (primarily insects and mites) that are parasites or predators of arthropod plant pests (known as entomophagous biological control organisms), and micro-organisms that infect arthropod plant pests (known as entomopathogens). They also include micro-organisms or arthropods that damage or feed on weeds (known as phytophagous or weed biological control organisms). These organisms are often imported from foreign countries for eventual release into the environment as natural enemies to exotic arthropod and weed pests that have been introduced into the United States. This practice is known as classical biological control. Because impact of these foreign organisms on the U.S. environment is not initially known, permit applications for importation of these organisms typically involve

developmental and host-specificity studies conducted in biocontainment facilities.

Other biological control organisms may be native to, but not widespread, throughout the United States and the impact of release in a new location is unknown. Some organisms may be field-collected rather than reared from pure culture, thus raising the potential for contamination with unwanted organisms. Sometimes permit applications for the movement of field-collected organisms are denied. Permits issued for movement of biological control organisms will include conditions requiring containment in a facility inspected and adequate for that organism when—

- the organism/isolate is new to the United States or the destination State and an EA or evaluation has not yet been conducted; or

- insufficient information exists to complete such an analysis or evaluation; or, importation of field-collected organisms or organisms whose origin are not laboratory colonies from an acceptable source; or,

- the organism was the subject of an EA and a finding of no significant impact cannot be reached, or adverse environmental effects were observed or are likely to occur based on environmental analysis.

Permits may be issued for importation of microorganisms of foreign origin without conditions requiring containment in a facility inspected and adequate for that organism/isolate when—

- the organism/isolate is an active ingredient in a current U.S. Environmental Protection Agency (EPA) registered pesticide; or,

- the organism/isolate was evaluated on the basis of host range and biological characteristics under different environmental conditions and found to be essentially equivalent to those same characteristics of domestic isolates of the same species/variety so it may be regarded as equivalent to an already established organism/isolate.

c. Laboratory Research

Importation and interstate movement of plant pathogenic micro-organisms, noxious weeds, and invertebrate plant pests requires a PPQ form 526 permit. The permit conditions required for movement of these organisms into biocontainment facilities are determined by the intended purposes of the applicant. A permit may be issued for intended uses such as research (lab, greenhouse and/or growth chamber), education (teaching), or diagnostic purposes. If the organism is on or in host material, then a separate permit is not required for the host material if that host material is

not intended for propagation. If the plant material is for propagation, however, then another permit may be needed. If soil is being imported for the purpose of isolating or culturing micro-organisms, then a PPQ form 526 permit is issued; a PPQ form 525 permit is issued when soil is imported for the purpose of physical and chemical analysis.

PPQ considers many factors as part of the review process. These factors include, but are not limited to: the need for a facility inspection, the need to obtain additional equipment or equipment certifications, and the need for additional information by PPQ or the State Department of Agriculture. Some applications bypass state review and are expedited if the State's concurrence for that organism is already on file. Guidance for the permitting of these organisms as well as lists of widely prevalent organisms are available at: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/SA_WPP/CT_wpp

PPQ is authorized to inspect shipments and/or facilities at any time to verify compliance with permit conditions. Issuance of a PPQ permit is contingent on compliance of the applicant with the regulations of other Federal, State, and local agencies (See section IV.C.5. and IV.C.6. for further information).

d. Continued Curation Permits

Continued curation permits provide continuity of permitting for researchers who do not want to receive additional isolates but, instead, only want to retain the organisms they already received under a prior permit. All permits are issued for a limited duration and often contain explicit instructions encompassing the destruction of organisms received under the permit. Destruction must occur either when the research ends or before the expiration date on the permit. Notification of the destruction of organisms must be made to PPB compliance officers per permit conditions. Coupled with restrictions limiting the ability of researchers to distribute organisms only to other individuals with permits, this regulatory structure ensures that organisms received under permits stay regulated by permits. Under these circumstances, the only way that organisms can legitimately be retained after a permit expires is for a continued curation permit to be issued.

The current electronic permit system was not originally designed for amending, renewing, or extending the duration of a permit. These limitations met recommendations from OIG, ensure permits stay linked to an inspected facility, and ensure contact information is updated. Subsequent modifications achieved increased permit processing

flexibility. Continued curation permits also allow researchers who received organisms identified only at higher taxa levels the ability to provide the species identifications to the PPB. For diagnostic laboratories, a continued curation permit fills the gap between the destruction requirements of diagnostic permits and the desire to retain organisms for research purposes.

Given these purposes, review of continued curation permits often consists solely of confirming the identity of the organisms, the permit holder, and current containment capabilities of the facilities. If the organisms are not moving, then risks inherent in importation, interstate, and intrastate movement do not need examination. If the facility met the necessary level of containment and those capabilities have not changed, then the risks associated with the use of those organisms were already analyzed prior to issuance of the initial permit. Consequently, verification of adequate containment is the primary consideration for continued curation permits.

4. Permitting Decisions for Release Permits

The decision to issue or deny a permit for release of an organism into the environment is based upon many environmental and pest risk factors. This section discusses the primary factors considered by the PPB permit analysts in their review of an applicant's request to move an organism to a location where it is likely to be released and survive in the natural environment. This section is organized based on the most frequent requests received by the PPB. There is, of necessity, some repetition of the information described previously for permitting decisions for contained organisms.

APHIS prepares EAs as part of the permitting process for every submitted PPQ Form 526 application. However, APHIS' NEPA Implementing Procedures (codified at 7 CFR part 372) recognize that permitting for certain low-risk organisms can be categorically excluded from requiring environmental documentation. One type of agency action subject to categorical exclusion includes permits for research and developmental activities that involve "releases into a State's environment that are either pure cultures of organisms that are either native or are established introductions" (7 CFR § 372.5(c)(2)(iii)(C)). To meet the requirements for a categorical exclusion, "the means through which adverse environmental impacts may be avoided or minimized have actually been built right into the actions themselves. The efficacy of this approach generally has been established through testing and/or monitoring" (7 CFR § 372.5(c)).

Analytically, many potential adverse environmental impacts can be quickly ruled out because the host range of the plant pest intended for release does not include humans or honey bees, the action is limited in

scope and/or isolated in effect, and does not involve pesticide release or bioaccumulation in the environment.

The majority of applications for environmental releases are relatively low-risk situations because the organisms are native or established and are released into small-scale field tests under conditions that are controlled in duration and scope. Higher risk scenarios differ in these parameters and, because they are evaluated on a case-by-case basis, permit conditions are adjusted to ensure risks are reduced to an acceptable level. If the risks cannot be mitigated to an acceptable level, then the permit is denied under the criteria in 7 CFR § 300.204.

a. Field Research

(1) Pest Invertebrates

Applications using invertebrate plant pests for field studies primarily involve crop or product testing for pesticide trials, university research, and Federal pest control efficacy work. The factors considered by reviewers include, but are not limited to: the natural range of the pest, distribution and abundance within this natural range, biology (reproductive capacity, overwintering data, host range, diseases vectored, etc.), life stages being tested, whether the pest is currently under eradication or a State or Federal management program or quarantine, whether the pest has any undesirable variants or subspecies, endangered species considerations, and supplier considerations.

Permit analysts consult with many people and review many sources, including previous permits and letters of denial, online resources, such as the CABI Crop Compendium (http://www.cabicompendium.org/cpc/home.asp), the University of Florida's "Featured Creatures" web pages, and other university cooperative extension websites and textbooks. If information is lacking or there are other concerns, State regulatory officials or APHIS personnel in the destination State are consulted early in the process to obtain local knowledge of the situation.

Permit conditions may require plowing, cages, and other measures or limits on the size of the field plots. The standard permit condition prohibiting further distribution without State and Federal approval precludes unauthorized distribution, even within a State. Permits are limited to the invertebrates themselves; work with plant diseases that the invertebrates may transmit originating from outside of the destination State requires a separate permit. The permit application must specify the location of all proposed field studies to, at least, the county or counties involved.

(2) Plant Pathogens

Environmental releases of plant pathogenic microbes require a PPQ Form 526 permit, and may involve bacteria, phytoplasmas, viroids, viruses, fungi, and/or nematodes. In general, greater potential for disease spread and long-term establishment in the environment is associated with increased pest risk and more restrictive permit conditions. As part of the review process for field releases of pathogens, PPB permit analysts consider the natural range of the target plant pest; its distribution, abundance, and host range; life cycle (including life stages to be released, reproductive capacity, over-seasoning stages, and ability to serve as a vector or be vectored); any variants, subspecies, or *formae speciales* likely to develop or being requested; the country of origin for the isolate to be released; the environmental parameters likely to affect the field test(s) in the area of release; the species of plant to be inoculated (if plant inoculations are planned); and whether there is an existing State or Federal management program or quarantine. Information sources include prior permitting history, letters of denial, the scientific literature (texts and articles), local State regulatory officials and/or APHIS personnel, and online resources such as—

- the Systematic Mycology and Microbiology Laboratory databases (SMML, available at: http://nt.ars-grin.gov/sbmlweb/fungi/index.cfm);
- the Widely Prevalent Fungi lists (available at: http://www.prevalentfungi.org/fungi.cfm);
- the USDA Nematode Collection (http://nt.ars-grin.gov/nematodes/search.cfm); and
- the Plant Viruses Online database (VIDE, available at: (http://sdb.im.ac.cn/vide/refs.htm).

For field releases, all of this information is analyzed to develop permit conditions that are designed to limit or reduce the potential for environmental impact under prevailing circumstances. Normally, permit conditions require some type of "clean-up" at the end of the field test, such as plowing or burning. For some plant pathogens, however, "dilution is the solution," particularly when the pathogen requires specific environmental parameters to persist in the environment, or when the population is not likely to be substantially different from the naturally occurring isolates within a region. For many plant pathogens, the concentrated inoculum moved interstate and intrastate prior to field release may carry an inherent higher potential risk to agriculture and the environment than the organisms once released (or "diluted"). For this

situation, the PPB develops permit conditions to control the movement of the concentrated inoculum.

Enforcement for a limited effect primarily occurs through permit conditions restricting the acreage to less than 10 acres. Acreage restrictions limit the initial inoculum load in the environment. If an unrestricted acreage was infested early in the season, then rapid progress of the disease over time (disease progress curve) would be expected (Van der Plank, 1963). By restricting initial infestations, the early or initial period associated with the disease progress can be somewhat extended so that high disease levels are less likely to be reached within the growing season, weather permitting (Agrios, 1988; Van der Plank, 1963).

Additionally, the analysis focuses on two factors. First, the distribution of the plant pest is researched to ensure the plant pest is a native or established introduction in the location requested for movement into the environment. The primary sources are reports within the scientific literature of the plant pest in that State or contiguous States. If the plant pest is not reported as present within that State and/or contiguous States, then the field release permit is denied. If the plant pest is reported as present within that State and/or contiguous States, then the permit conditions are likely to include testing and/or monitoring requirements. The reporting usually takes the form of notifications made to the PPB when a plant pest is released and when the field testing is ended.

APHIS reserves the right to inspect facilities and fields at any time to verify compliance with permit conditions. PPB permits require compliance with the regulations of other Federal, State, and local agencies (see chapter 4, sections C.5. and C.6. for further information).

b. Butterfly Releases

The PPB issues permits for nine species of butterflies for one-time releases into the environment for certain occasions, such as ceremonies and celebrations, within the continental United States. Please note that some of these species are being considered exempt from permitting requirements under the proposed rulemaking. These permits are managed differently than the practice where the recipient of the regulated organisms is the permit holder. For these butterfly release permits, the PPB facilitates business by permitting the supplier rather than the recipient (customer) who could be a one-time only purchaser. The nine butterfly species are released only in States where they are common, and there is no evidence of genetic differences among the geographic locations involved. The nine species approved for release are: *Agraulis vanillae* (gulf fritillary), *Danaus plexippus* (monarch), *Heliconius charitonia* (zebra or zebra longwing), *Heraclides cresphontes* (giant swallowtail or orange dog), *Nymphalis*

antiopa (mourning cloak or Chamberwell beauty), *Papilio polyxenes* (black swallowtail), *Vanessa atalanta* (red admiral), *Vanessa cardui* (painted lady), and *Vanessa virginiensis* (American lady). Many of these species are migratory or show migratory tendencies and, therefore, have low genetic variability. A matrix of the butterflies that are allowed for release in each State is available at: http://www.aphis.usda.gov/plant_health/permits/organism/downloads/decision_chart.pdf.

Permit conditions specify that fewer than 250 butterflies of one species may be released into the environment at one time/location, and wild-caught butterflies may not be released. APHIS has issued permits for the interstate movement of the monarch butterfly, *Danaus plexippus*, and the painted lady butterfly, *Vanessa cardui*, since the early 1960s. These two species constitute the majority of the butterflies that are released. The highly visible monarch butterfly shows evidence of geographic differences in eastern and western variants of a microsporidian pathogen that infects this species. Consequently, permit conditions do not allow monarch butterflies reared in the Western United States to be released in States east of the Rocky Mountains, and vice versa. Permit conditions typically require records of all shipments be kept for 3 years, and be available to the PPB upon request. Shipping of butterflies for a permit holder by a third party is not allowed unless the third party also has a permit for shipping to the destination State.

c. Sterile Insect Releases

Permit applications for release of sterile insects are made with the intent of controlling a given pest species. For these species, sterile insects are effective as a result of the adult behavior of mating only once during their lifetime. Those insects mating with sterile insects do not produce viable progeny, and the pest population is lowered commensurate with the pest's loss of successful reproduction. The PPB considers a number of factors when evaluating applications for the release of sterile insects as part of a pest management or eradication program. Permit applications for mass releases of sterile insects have been limited to APHIS programs because the complexity and costs of such production limit its use to broad agricultural applications. PPB permit analysts may contact the appropriate PPQ National Policy Manager in Pest Management to ensure that they are aware of, and in agreement with, any proposed releases.

In these release situations, the efficacy of the sterilization method is a critical consideration. Each shipment must be accompanied by a letter from the director of the facility certifying that the released insects are sterile. Documents detailing the method of sterilization also may be required. The appropriate State department of agriculture regulatory

officials and the SPHD are consulted as part of the permitting process for these releases.

d. Permits for Fish Bait and Pet Food

Import permits are issued to applicants for a variety of organisms used as fish bait and pet food. The nature of this intended use implies that environmental releases will occur. Specific permit conditions may be designed to mitigate the potential risk of dissemination of plant pests. Factors considered in the permit conditions are the biology of the organism, the life stage being imported, rearing procedures, treatments prior to importation, and the organism's potential to become a plant pest once released to the environment.

Permits are issued for the importation of earthworms for use as fish bait. The major agricultural risk of importing earthworms is based on the earthworm's biology and habitat. Most annelid worms used as fish bait are soil dwellers; therefore, plant and livestock diseases present in the soil in the country of origin could be imported in the gut of these earthworms. APHIS conducted a risk assessment that addressed the environmental consequences of importing earthworms with an emphasis on the potential for disease importation. The agricultural risk posed by the importation of earthworms is mitigated by altering their diet to eliminate soil from the earthworm's gut prior to shipping. Guidance for obtaining permits for the importation of earthworms is available at: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/SA_Earthworms/CT_Earthworm.

Import permits are issued for mealworms, *Tenebrio molitor*, for use as small animal pet food and bird feeders. Mealworms may be imported if they are reared under conditions similar to that of earthworms to preclude importation of plant and animal diseases in their gut flora. As a pest of stored grain, the mealworm is associated with agricultural settings, and has the potential to carry plant and animal diseases. Collaboration with APHIS–Veterinary Services on these permit applications is designed to preclude potential animal disease risks. Guidance for these permits is available at: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/SA_Animalfeed/CT_Petfood_fishbait_animalfeed.

Import permits for the larval form of a Chilean moth, *Chilecomadia moorei*, known in the pet trade as butterworms, authorize their subsequent distribution as pet food. These larvae are desirable as pet food because of their large size and lack of stinging body parts. Even though these larvae

are plant pests, an acceptable irradiation treatment prior to shipping in the country of origin allows importation into the United States. An original irradiation certificate must accompany each shipment, and be verified at the port of entry into the United States by a Federal inspector. Guidance for these permits is available at: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/SA_Animalfeed/CT_Petfood_fishbait_animalfeed.

e. Import Permits for Snails Sold as Aquarium Pets

The PPB issues permits to applicants that authorize the importation of freshwater snails for use in the hobby trade. The permit conditions require an inspector at an APHIS plant inspection station to verify the identity of the species imported and remove contaminants. Most species of freshwater and all marine snails are not considered plant pests, and may move throughout the United States without permits. However, one family of freshwater snails (Ampullaridae) is known to include voracious plant feeders. These snails are not authorized for importation with one exception—Ampullarid snails in the *Pomacea diffusa* complex, namely *Pomacea bridgesii* and *P. diffusa*. These species are algae feeders and do not pose foreseeable risks to agriculture. Once an inspection verifies the identity of the snails as part of the *P. diffusa* complex, the snails may be subsequently shipped to all continental United States destinations, and interstate movement permits are not required. Guidance for plant pest movement permits for other species of snails is available at: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/sa_snails_slugs/ct_snails_slugs.

f. Entomophagous and Entomopathogenic Biological Control Organism Permits

A PPQ Form 526 permit is required for importation of entomophagous and entomopathogenic biological control organisms used for direct release into the environment, research in the field, greenhouse applications, field cage studies, and environmental release. It is current APHIS policy that a permit may be required for interstate movement for these purposes, depending on the species of the organism and other factors, as explained below.

Before each permit is issued, the conditions for the proposed movement and release are evaluated to determine the risk of pest dissemination. For example, this could occur if the proposed methods to collect and transport biological control organisms allow the inclusion of noxious weed seeds or plant pests. This evaluation is used to create permit conditions to negate

or significantly reduce these risks. Both biological information and information on the history of use and environmental release of the organism are considered before the issuance of a permit. Typical issues considered include the host range, areas of establishment (worldwide and in the United States), and where the organisms to be moved were originally collected. Permitting decisions, as described below, are recognized as different categories:

1) The organism is widely established in the United States (within its potential range) and has not caused adverse environmental effects throughout this range. In this case, a permit may be issued for environmental release.

2) The organism has been released and/or is established but only in part of its potential geographic range. In these cases, a permit is issued for environmental release only in those States where establishment or prior releases are documented.

3) The organism is new to the United States or new to the requested destination State. In these cases, the permit is not issued and an environmental evaluation is conducted.

4) The organism is established in the United States in at least part of its potential range, but the source (where collected) of the specimens proposed for release is significantly different from those that are already established. Examples include origins from: (a) hosts not normally associated with the organism, (b) different continents or distant locations on the same continent, (c) nontypical climates or habitats not normally associated with the organism, and (d) varietal types or subspecies differing from established types. All foreign isolates of microbial entomopathogenic biological control organisms are included in this category because these foreign isolates are distinguished and evaluated as potentially different organisms from those of the same species that are established in the United States. In all these cases, a permit is not issued and an evaluation determines if biological equivalency occurs. When biological equivalency exists, a permit may be issued.

5) The organism is established in at least part of its expected range in the United States, but adverse environmental effects have been observed or are deemed likely to occur. In these cases, a permit for environmental release is not issued.

For entomophagous and entomopathogenic biological control organisms that are new to the United States or parts of the United States, the applicant is required to petition an external panel of independent subject

experts in biological control associated with NAPPO. This Biological Control Review Committee formalized their analysis procedure in NAPPO regional standards phytosanitary measures (RSPM) No. 12, "Guidelines for Petition for First Release of Non-Indigenous Entomophagous Biological Control Agents" (NAPPO, 2015b). The petition submitted by the applicant should conform to the outline presented in RSPM No 12. Review by this NAPPO committee includes examination of information including—

a) taxonomy, method of identification, and source of organisms;

b) the native and current geographic and climatic distribution of the species to evaluate the establishment potential;

c) host range of organism proposed for release;

d) potential direct and indirect impacts to nontarget species, including federally listed threatened and endangered species; and

e) potential impacts on other biological control organisms.

After review of the petition, the NAPPO Biological Control Review Committee issues a recommendation with comments to APHIS for consideration. After evaluation of these recommendations, APHIS then fulfills regulatory procedures required for compliance with the ESA, NEPA, and other acts or directives that apply. After the completion of this environmental analysis, if a finding of no significant impact (FONSI) is reached, then a permit for environmental release may be issued. If a FONSI cannot be reached, then a permit for environmental release will not be issued.

Certain species of entomophagous biological control organisms are produced by private companies and sold in the United States for augmentative releases. Most of these species have a long history of use, and most production of specimens occurs in Canada and Europe. These species are either established in the United States or are unlikely to establish, and there are no reported adverse environmental impacts associated with previous releases into the environment. The PPB may issue an import permit for environmental release for organisms meeting these parameters on a case-by-case basis. It is APHIS' policy that these commercial entomophagous biological control organisms, which have been permitted for importation, are subsequently permitted to move interstate without additional permitting. Similarly, a PPQ Form 526 permit is required for the importation of strains (of a specific isolate) of entomopathogenic microbes that are active ingredients of pesticides

registered by EPA. These entomophagous microbes also do not require additional permitting for interstate movement.

g. Weed Biological Control Organism Permits

A PPQ Form 526 permit is required for both the importation and the interstate movement of weed biological control organisms intended for environmental release. Organisms released for use as biological controls of weeds may be arthropods, nematodes, or microbial pathogens. Permits for importation of these organisms generally require them to be received and maintained in biocontainment facilities, as described previously in this chapter in section C.2, Biocontainment Facility Requirements. The PPB also issues permits for first-time environmental release from containment of nonindigenous weed biological control organisms. Further, the PPB issues permits for interstate redistribution of approved weed biological control organisms. A PPQ Form 526 permit is not needed for interstate movement when pathogens used for weed biological control are listed as an active ingredient in an EPA-registered product.

Permits for first-time releases of nonindigenous weed biological control organisms are issued only after a scientific review of the potential effects of the release. RSPM No. 7, "Guidelines for Petition for First Release of Non-Indigenous Phytophagous and Phytopathogenic Biological Control Agents" (NAPPO, 2015a) describes the information that researchers must provide to the PPB before the release of new organisms can be permitted. Information requested includes aspects of the biology, regulatory status, distribution and economic impact of the target weed, and host specificity of the proposed biological control organism, its expected impact after release, and post-release monitoring plans.

For first-time releases of weed biological control organisms, an advisory group composed of Federal regulators and researchers (known as the Technical Advisory Group for Biological Control Agents of Weeds (TAG) (https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/biological-control-organism-permits/sa_tag/ct_technical_advisory_group_biological_control_agents_weeds) provides assistance to APHIS. TAG evaluates the scientific information submitted by researchers requesting first-time environmental release of nonindigenous weed biological control organisms in the continental United States. TAG makes recommendations to APHIS that are used in support of permitting decisions. Once the TAG recommends release of an organism, APHIS proceeds with the preparation of an environmental evaluation of the release based on their assessment of those recommendations. For APHIS' approval of new organisms proposed for

release in the United States or its territories, compliance with environmental statutes (such as NEPA and ESA) is required.

For interstate movement of weed biological control organisms that APHIS approved for environmental release, permits accompany the movement of the organism to the site of release. If the organism is widely established in the United States (within its potential range) and has not caused adverse effects, a permit may be issued for interstate movement for environmental release. If the requested organism is established only in part of its potential geographic range, permits may be issued for release only in those States where establishment or prior releases are documented. If the organism is new to the requested destination State, a permit is not issued until an environmental evaluation is conducted.

Once approved for environmental release, the main concern regarding the released species is verification of identity and purity of the organisms. For both importation and interstate movement of approved weed biological control organisms, permit conditions may require that the species are reared in laboratory colonies, their identification is verified, and that the organisms are free from contaminant species, such as hyperparasites or propagative parts of noxious weeds. These conditions are to ensure that unwanted organisms, whether contaminants or misidentified biological control organisms, are not spread to the destination location to cause unintended consequences.

5. Permitting Decisions for Soil

The PPB issues two types of soil permits, depending on the intended use for the soil. A PPQ Form 526 permit application encompasses requests for the isolation of living organisms that could be plant pests. This type of permit focuses on the organism(s) to be isolated rather than the soil itself. The other type of soil permit is the PPQ Form 525A which covers other intended uses, including DNA/RNA analysis. Numerous plant and animal diseases and pests may be present in nonsterile soil; therefore, soil from foreign and from some domestic origins must meet certain safeguarding requirements specified in 7 CFR § 330.300 to ensure safe movement into and within the United States. Guidance pertaining to soil permits is available at:
https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/sa_soil/ct_regulated_organism_soil_permits_home

PPQ Form 525A applies to interstate movement of soil from Hawaii and U.S. territories, and for importation from foreign sources. Both interstate and intrastate movements of soil from areas that are under Federal quarantine are regulated under 7 CFR part 301. A PPQ Form 525A permit is not required for soil regulated under 7 CFR part 301; however, the applicant must sign a Federal compliance agreement with regulatory

officials of the destination State. Information pertaining to soil types and intended uses that can be authorized by this permit (provided safeguarding conditions can be met) is available in the soil circular [Circular Q–330.300–1, Soil (01/2010) Revised (USDA–APHIS, 2008)] from the above web site link. This answers the most common questions regarding how to import and move soil. Currently, soil importations from most parts of Canada are exempt from permit requirements, in accordance with 7 CFR § 330.300.

Sterilized soil does not require safeguarding and, therefore, can be moved into and through the United States without further restriction. In contrast, permitted nonsterile soil is not authorized for environmental release. Soil imported in volumes greater than 3 pounds, and soil imported in volumes less than 3 pounds that cannot be sterilized because the treatment interferes with its intended use, is only authorized to move into a facility that is inspected and approved by PPQ. Imported soil in volumes less than 3 pounds can be directed to an APHIS Plant Inspection Station to undergo sterilization treatments.

Applications to move nonsterilized soil to an inspected facility are initially reviewed by plant health and regulatory officials of the destination State. For each State, a SPHD and a State department of agriculture plant regulatory official developed a compliance agreement that provides specific guidance for the mandatory safeguarding measures pertaining to the movement of this nonsterilized soil. The procedures for meeting safeguarding requirements are included in standard operating procedures developed and maintained by the facility. The compliance agreement must be signed by the applicant, a State department of agriculture official, and a SPHD of the destination State prior to the issuance of a Federal permit. APHIS maintains a list of inspected and approved facilities which is available at: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/sa_soil/facilities.

Prior to issuing a permit, the PPB may also consult with State regulatory officials or APHIS personnel in the destination State to obtain local knowledge of the safeguarding practices.

D. Permit Process Analysis and Permit-Specific Review

This EIS is designed to be a broad analysis of the proposed and existing permit processes that pertain to the movement of soil, plant pests, and other regulated articles. It focuses on the review process and those procedures that guide the associated agency decisions. Agency permitting decisions to preclude plant pest risks include (a) the issuance and denial of

a permit application, (b) the fulfillment of a permit holder's request to withdraw a permit application, and (c) the amendment or cancellation of a permit at the request of the permit holder or the amendment or revocation of a permit. This document is not intended to serve as an encyclopedic compendium of information about biological control, history of environmental impacts from plant pests, or permit applications for specific plant pests. It does not consider documentation for APHIS program releases of biological control organisms, or sterile insect releases of plant pest species. Instead, this EIS focuses on providing an overview of the permit process and associated methodology. Much of the permitting process methodology is described in previous documents; permitting requirement descriptions, permit templates, and various guidelines are cited, summarized, and incorporated by reference in this EIS to clarify the process.

In addition to providing a broad overview, this EIS also describes specific procedures that APHIS intends to follow prior to issuing any permit to move a plant pest to ensure that site-specific characteristics and organism-specific characteristics are considered in decisionmaking. For example, the current regulations for issuing a permit to move a given plant pest in 7 CFR § 330.201(a) requires the applicant to submit 13 types of information for agency consideration prior to any decision by the PPB. Permit-specific environmental reviews required by Federal and State regulators are coordinated to improve efficiency. These permit-specific environmental reviews will summarize and tier to the permit process analyses contained in this EIS when addressing potential cumulative impacts and any broader permit process issues that must be analyzed. Permit-specific reviews will consider such things as the biology, identification, host specificity, dispersal mechanisms, regulatory status, distribution, economic impacts, and potential environmental impacts of the target plant pest or noxious weed.

After publication of this EIS, APHIS will continue to consider new scientific developments related to biological control and plant pests, new findings related to potential risk to humans or other nontarget species, and the relationship to other developments in control technology, including biotechnological applications. Although this EIS does consider reasonably foreseeable scientific development, the extent to which new technology may require APHIS to revise or adjust the permitting process is likely to cause the agency to revisit some issues on a periodic basis.

The analysis of organism-specific permit applications considers the circumstances, issues, and needs of the applicant; however, the ability to process any application depends upon the completeness of information provided by the applicant and the potential environmental impacts to be considered. Some permit applications may be eligible for categorical

exclusion from NEPA documentation. If the organism is eligible for this category and there are no State concerns regarding the movement or release within its jurisdiction, then the application's analysis may be minimal to reduce processing time. For permit applications related to organisms lacking historical release data, APHIS documents existing information and meets the appropriate NEPA implementing requirements. The other Federal and State agency actions associated with the permit process are discussed in greater detail in chapter 4, section C.5., Special Permit Process Considerations. In some cases, voluntary groups may review information provided by the permit applicant and provide APHIS with recommendations on the pending decision. Specific consultative and advisory processes relating to permitting are discussed in chapter 4, section C.6., Special Permit Process Considerations.

II. Alternatives

APHIS analyzed three alternatives and their associated components in this EIS. These alternatives are broad in scope and reflect the need to consider potential environmental impacts resulting from decisions reached for permit applications. Representative EAs prepared for permit applications for biological control of weeds are available at: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/plant-pest-and-disease-programs/sa_environmental_assessments/ct_biocontrol_weeds.

Findings from previously completed EAs are cited in this EIS; however, the focus is on potential cumulative impacts from the permit process rather than impacts from individual movements or associated actions. This EIS is not intended to provide a detailed analysis for all methods of movement of all plant pests, biological control organisms, and associated articles. It does, however, present a comprehensive review of the potential impacts (primarily indirect and cumulative) associated with regulation of movement of plant pests, biological control organisms, and associated articles under 7 CFR part 330. These impacts may vary in their intensity and may be considered positive, neutral, or destructive, based upon individual perspective. To the extent possible, this document will describe these effects relative to the viewpoints of interested parties to ensure that all known perspectives are presented for the decisionmakers to consider.

The alternatives to the methodology used in the permitting process for regulated articles are presented in a manner that clarifies the environmental issues and the pest permitting choices made regarding permit requests. Applications are received and their disposition ranges from the denial of an application to an issued permit. Applications may be denied for any of the reasons in 7 CFR § 330.204. These reasons may include: (1) acceptable safeguards cannot be arranged, (2) the risk for destructive potential outweighs the probable benefits, (3) past violator status or the applicant demonstrated an unwillingness or inability to meet permit conditions, (4) the pest's movement conflicts with an APHIS program, or (5) objections from a State. Issued permits may be cancelled for similar cause. Applications may be denied in part, and can be withdrawn at the request of the applicant at any time. Issued permits may be amended upon request by the permit holder, and are considered on a case-by-case basis. When a permit holder leaves an institution or dies, the PPB staff ensures the regulated organisms are either destroyed or a new permit is issued, in a timely fashion, to a responsible party.

The alternatives considered in this EIS are the following: (1) no action, (2) the proposed revision of part 330 regulations, and (3) a comprehensive risk mitigation program. The alternatives and associated components vary with regard to their practicality or feasibility based upon environmental,

scientific, regulatory, economic, and logistical considerations. They may also vary considerably with regard to the effectiveness of the measures, capability to attain permitting objectives, and timely applicability under current restraints on human and fiscal resources. Selection of specific methods for certain permit requests requires further documentation (see chapter 4, sections C.5. and C.6. regarding consultation and other approvals associated with the process). This EIS is designed to clarify the criteria that form the basis for future decisions regarding permit requests, and to identify the potential impacts to address when documenting these decisions.

A. Description of Alternatives

There are potential environmental consequences for each of the alternatives, including the no action alternative. Environmental consequences result from permitting decisions on the regulation of plant pests, soil, and associated articles. Agency permitting decisions to preclude potential plant pest risks include: (a) the issuance and denial of a permit, (b) the fulfillment of a permit holder's request to withdraw a permit, and (c) the amendment, cancellation, or revocation of a permit. Those consequences are not a direct result of the decision, but are indirect results from the actions of the applicant to move or release the plant pest organisms. Although individual permit decisions are not likely to differ under each of the three alternatives, their potential environmental impact, under some alternatives, is expected to vary with the permit conditions or required methods to mitigate potential risks. In particular, the third alternative for a comprehensive risk mitigation program makes allowance for more extensive permit conditions to preclude specific potential impacts associated with specific permits. This chapter describes the components of each alternative and compares their relative ability to address and mitigate potential environmental and pest risks. The specific environmental impacts, risk issues, questions of uncertainty, and unknown effects are discussed in chapter 4, Environmental Consequences.

A general comparison of the alternatives is presented in table 2–1. This table allows comparisons among the alternatives regarding the manner of handling specific logistical issues. The no action alternative (current 7 CFR part 330) forms the baseline for this comparison. The other alternatives may require comparable effort, more effort, or less effort to fulfill the regulatory provisions. This allows the decisionmaker to evaluate input and outcome from the selection of each alternative. The table shows the relative benefits of each alternative. If time, money, and resources were not limited, the Comprehensive Risk Mitigation Program alternative would offer the most thorough regulation.

Table 2–1. Logistical Comparison of the Alternatives to No Action.

Issue	Alternative		
	No Action (current 7 CFR part 330)	**Proposed Revision of Part 330 Regulations**	**Comprehensive Risk Mitigation Program**
Timeliness to Issue Permits	Present pace	More rapid on average	Reduced due to additional workload
Cost/Application to Program	Current	Comparable or reduced	Increased due to additional requirements
Personnel Required	Additional staffing needed	More efficient use of personnel	More staffing required
Travel Required	Current	Comparable to no action	Increased travel for monitoring and enforcement
Basis for Regulatory Approach	Status quo	Improvements in efficiency	Lower risk tolerance
Permit Application Analysis Time	Status quo	Reduced	Increased
Transparency of APHIS Regulations to Applicant	Limited	More transparent	Less transparent due to increased complexity
Protection Against Unintentional Release in Accidents (Packaging Requirements)	Minimal stipulations for packaging or transport	More extensive packaging and transport requirements	Highly extensive packaging and transport requirements
Purity of Permit Organisms	Assumed	Certification process	Rigorous certification
Containment Requirements	Status quo	More biosecurity	Most biosecurity
Allowance for Unknowns and Uncertainties	Status quo	Comparable to no action	None
Methods for Reducing Permit Analysis	Courtesy permits and oral permits	Exceptions from permitting	None

The no action alternative maintains the status quo, but includes some practices no longer deemed acceptable for permit regulation. The preferred alternative provides approaches to deal with outdated practices, as well as enhances paperwork reduction, focused reviews, biosecurity, and regulatory transparency.

Some components of the comprehensive risk mitigation alternative may not yet be ready for implementation with the current level of knowledge and permit infrastructure; however, those components could be part of future revisions to the regulations as the permit process changes to meet future challenges and opportunities. A comparable table is provided in

chapter 4 (table 4–1) to compare the level of information needed and their likely outcomes from selection of each alternative.

1. No Action

The no action alternative is characterized by no change in the existing regulations. The proposed revisions to the current regulations would not be promulgated under this alternative. Although continuation of the current regulations does not contribute to the further mitigation of plant pest risks, the analysis of the no action alternative provides a baseline for comparison to the other alternatives, and is required by NEPA and its implementing regulations.

Continuation of the current regulations, as described in the current 7 CFR part 330, does not take into account the new methods and improved technology for handling plant pests, biological control organisms, weeds, and associated articles. It does not leverage the experience gained from the ongoing review of current permitting practices, nor does it provide the flexibility for dealing efficiently with mitigation conditions for pest risk potential of the different organisms under permit. For example, some permit applications could be readily expedited under the proposed rulemaking. In particular, those biological control organisms that are established throughout their geographical range in the continental United States (such that additional releases of pure cultures of the organisms into the environment will result in no significant impacts on the human environment) could be expedited for interstate movement or environmental release. Many of these organisms were analyzed by APHIS for their actual risk to plants, but are now subject to the same review process as all other requests under the current regulations. The better use of time, experience, and resources, under the proposed regulation, allows PPB permit analysts to focus more time and effort on those organisms posing higher plant pest risks. Nevertheless, the difference in environmental impacts between the permitting processes, under the two alternatives for some decisions, may be limited to issues such as paperwork reduction. The finite available fiscal and human resources of the PPB make focus on the more challenging plant pest risks posed by organisms and associated articles increasingly important.

The no action alternative would maintain the definitions, policy, and regulations of 7 CFR § 330.100–212 as amended through April 27, 2001 (66 FR 21058). The last amendments to these regulations were promulgated in 2001; however, there were no substantive changes regarding how the permit process is conducted. Although the current regulations do not preclude use of the risk-based criteria proposed in the preferred alternative, those criteria are not clearly specified as components of the decision process. In addition, the no action alternative does not involve explicit regulations for arthropod and weed biological control organisms. The proposed revisions to the permit requirements for

packaging and labeling would not be promulgated under this alternative. There would be a lack of regulations established for biocontainment facilities in which plant pests, biological control organisms, and associated articles would be maintained. Unlike the proposed regulation, the no action alternative would continue to allow the practices of courtesy permits (7 CFR § 330.208) and oral permits (7 CFR § 330.203). Although these practices may be conducted in a manner to mitigate potential pest risk, the lack of documentation and defined process do not preclude the inherent difficulties and pest risks associated with these blanket permits. The special permits for national defense projects and for movement of organisms by other Federal agencies, as covered under 7 CFR §§ 330.206 and 330.207, would remain.

PPB permit analysts design the permit conditions and mitigations to protect human health, nontarget species (including threatened and endangered species), sensitive areas, and other parts of the environment potentially affected by movement of plant pests, biological control organisms, and associated articles. Issuance, denial, and conditional issuance of permits for movement may be made by PPQ based upon plant pest risks or risks to these other components of the human environment. However, the present criteria for issuance of a permit are not clearly provided to the public. The proposed regulations identify the type of data used to assess risk and make informed decisions about permits for movement.

Continuation of the no action alternative could fulfill APHIS' mission. It would, however, not take advantage of the improvements in efficiency afforded by the proposed regulations. It would not clarify the criteria that form the basis for decisions to issue or deny permit requests to the applicants and other interested stakeholders. Many of the current regulations are outdated and do not specify the key factors that form the basis for the permit process. It is important to consider how this regulatory framework influenced the policy and practices for decisionmaking related to permit applications. The experience gained from those permit process decisions forms the basis for the proposed revisions now under consideration.

2. Proposed Revision of Part 330 Regulations (Preferred Alternative)

This alternative is the preferred alternative for regulation of the movement of plant pests, soil, biological control organisms, and associated articles for the purpose of consistency with the PPA. Implementation of this alternative updates and clarifies policy and practices that evolved as PPB permit analysts reviewed permits and interpreted the current part 330 regulations, as discussed in the no action alternative. The primary changes involve creating exceptions to the need for a movement permit for organisms that the agency determines do not pose a plant pest risk, and exemptions from permitting for certain soils. Permits for movement of soil and plant pests would continue to be issued or denied; however, the

identification of organisms excepted from needing a permit would reduce the number of permits issued. The proposed regulations identify a process for establishing and maintaining the lists of excepted organisms. The requirements for movement, labeling, and packaging of soil and plant pests are revised and clarified to enhance biosecurity under the proposed regulations. In accordance with PPA section 413 (7 U.S.C. § 7713), organisms listed as exceptions to needing a permit could not be inspected and held at a port of entry. This includes plant pests and biological control organisms listed as exceptions under the proposed process. In contrast, packages containing soil and associated organisms established as exemptions under the proposed regulation would continue to be subject to inspection and agricultural holds at the port of entry. The two types of permits (for soil and plant pests) are described in greater detail in chapter 2, section B.1., Types of Application Forms.

A biological control organism, under the PPA, is defined as "any enemy, antagonist, or competitor used to control a plant pest or noxious weed." Organisms that meet this definition were regulated primarily as plant pests, and secondarily as biological control organisms. In other words, permitting conditions for the movement and environmental release of these organisms promote safeguarding. The rule would require permits for the importation, interstate movement, or environmental release of most biological control organisms. It would, however, create a category of biological control organisms recognized as excepted from permitting requirements for interstate movement and/or environmental release. Organisms that have become established throughout their geographical range in the continental United States and that the additional release of pure cultures of such organisms into the environment of the continental United States will present no additional plant pest risk to plants or plant products.

The conditions for movement of plant pests into and through the United States to biocontainment facilities or to a final destination are specified within the proposed regulations and are described in greater detail in this chapter, section B.4, Conditions for Packaging and Transport. All facilities must be determined by APHIS to be constructed and maintained in a manner that prevents the dissemination or dispersal of plant pests, biological control organisms, or associated articles from the facility as part of the permitting process. APHIS will make available web-based guidance regarding biocontainment facilities. Means of transport, packaging, and labeling requirements are stipulated for movement of the organisms in addition to any specific packaging requirements in the permit conditions. Specific conditions were agreed upon by CBP for the hand-carry entry of plant pests, biological control organisms, and soil.

The proposed regulations do not allow for a number of circumstances permitted under the current regulations. An oral permit without conditions, as under the current 7 CFR § 330.203, could no longer be issued. Courtesy permits (7 CFR § 330.208), national defense project permits (7 CFR § 330.206), and permits for movement by other agencies (7 CFR § 330.207) would no longer be issued or recognized as valid under the proposed regulations. These permits generally are not issued by APHIS, and the lack of regulatory oversight for them creates potential difficulties for enforcement of permit conditions and mitigation of plant pest risks. Although APHIS has the authority, under the PPA, to issue permits for the movement of a vertebrate herbivore of a noxious weed, no permits of this type have been issued to date.

3. Comprehensive Risk Mitigation Program

A primary function of the PPB involves responding to applications to issue permits to move live plant pests, including potential biological control organisms and pollinators, noxious weeds, and soil. These requests come from a wide range of applicants for movement of a wide range of organisms (see chapter 1, section C, Scope and Focus of This Environmental Impact Statement). The decision to issue or deny a permit is based on considerable technical information about the organisms or soil identified in the application. The experience gained from extensive review and evaluation of permit applications and associated pest risk over the past few decades has provided APHIS with a solid basis for expanding regulatory functions to address more specific risk-based categories. This resulted in considerable expansion of the PPB staff to deal with issues associated with the perceived plant pest risks. However, the wide range of organisms, variation in the manner of containment, movement, and uses by the various applicants make implementation of a more effective risk mitigation program a daunting task.

As an alternative, APHIS may not yet have sufficient data on the human, fiscal, and infrastructure resources needed to implement a risk-based category approach for pest permitting regulation. Nevertheless, aspects of this alternative, if not yet within reach, may be considered for future improvements to the plant pest permitting practices. In spite of currently limited resources, it remains a reasonable alternative because the components are feasible even if this approach is not supported by current policy. Therefore, this EIS carefully considers aspects of this alternative with the recognition that implementation of certain components of this approach to regulation may be contemplated in the permitting process as the agency continues to develop better methods to review and evaluate permit applications. This alternative involves a broad risk mitigation strategy to preclude pest and environmental risks, as well as increase the use of monitoring and provide provisions to remediate unforeseen impacts. Although the PPB currently issues permits based upon the level of risk presented by a given organism with conditions regarding the packaging,

labeling, means of transport, containment, and movement, including environmental release requirements, more extensive oversight and enforcement of permit conditions could enhance the prevention of unintended consequences. Over the years, the PPB has improved permit oversight and facility inspection, and would continue to do so as needs arise and infrastructure and resources are available.

This alternative would include increased verification of compliance with protection measures by the permit holder. Safeguards for biocontainment facilities for certain organisms would be required based upon potential pest risk and proximity of the facility to susceptible host plants. Phytosanitary measures for personnel, supplies, and organisms entering and leaving the facility would be tailored to the degree of risk (similar to biocontainment level requirements). Ideally, all biocontainment facilities receiving permitted organisms would be personally inspected by APHIS personnel, and a schedule of inspection would be initiated to ensure ongoing compliance with the biosecurity provisions. The PPB would verify proper disposal of permitted organisms that ceased to be reared at the facility. Automatic notification reports due from permit holders, such as records of organisms maintained within a facility, would be required.

Inspection of all overseas facilities that send organisms to the United States for direct environmental release, (e.g., for commercial shipments, biological control organisms, and earthworms for fish bait) would be a part of the process under this alternative. Although permit conditions consider issues like contamination and pure cultures carefully, there currently is limited review of the suppliers in other countries. The verification of identity of all organisms and the purity of cultures imported into the United States would be standard procedure. All shipments of imported organisms would be subject to required electronic bar code scanning for labels entered at ports of entry and their automatic tracking in the APHIS electronic permitting system. Current practices allow manual entry of the label bar code, and only some ports use bar-code scanners. This alternative would include site visits as part of the review and evaluation process for permit applications encompassing unique movements of biological control organisms or plant pests into the environment.

Under this alternative, host-specificity testing prior to movement of organisms into the environment would continue to be based upon the known hosts, related potential host plants, potential pest risk, and known organism-plant interactions. There are several factors that would be incorporated into host-specificity testing for arthropod biological control.

In addition to the standard scientific literature review, the required host-range assessment would include review of museum records, field observations in the area of origin, physiological observations, behavioral

observations, and ecological observations and experiments (van Lenteren et al., 2006). Verification of proper identification of the organism and evidence from testing to ensure that those organisms contain no contamination from other exotic species (e.g., parasites and parasitoids) or potentially pathogenic micro-organisms would be required. Host-specificity testing would include geographic considerations affecting subspecies and potential for introgression or hybridization.

In this comprehensive alternative, monitoring provisions would ascertain the extent of establishment, spread, and limit to expected hosts. Monitoring would be required of the permit holder for those nonindigenous biological control organisms released for the first time. Mandatory reports of monitoring results would be submitted to the PPB. Site visits would be scheduled by APHIS. Information on the outcome of releases permitted over time would be used to refine reporting requirements. This would include information about the establishment, efficacy, nontarget impacts, and characteristics of the released organism.

Under this alternative, there would be extensive administrative categories. For permitted organisms to be contained, this would include administrative categories for the type of establishment (e.g., educational facility, snail farm, zoo, butterfly house, biological supply company, research lab, and mass-rearing facility) and the level of containment needed (i.e., highest for select agents and reduced, based upon the level of plant pest risk). For organisms to be moved into the environment, administrative categories would be based on the type of movement into the environment (e.g., cage test, geographically isolated, or general continental), purpose of movement (e.g., field research, biological control, sterile insect releases, special occasion butterfly releases, fish bait use, pet food, and weed biological control supply companies), and the level of plant pest risk associated with the organism. The conditions for each permit would be tailored to the administrative category unless information or additional evidence suggests the need for more stringent or less stringent requirements.

Selection of the comprehensive risk mitigation program alternative involves a substantial expansion of the current permitting process. It provides the most mitigation of potential environmental and pest risks of the three alternatives; however, it also requires the most extensive regulatory infrastructure and fiscal resources of the three alternatives. Although APHIS' understanding of more effective means to administer the permitting process continues to improve, the logistic considerations for expansion to this level of regulation are not yet adequately elucidated to implement this entire approach for fulfillment of the agency permitting process.

B. Component Methods of the Preferred Alternative

The component methods of the preferred alternative involve permitting practices that are designed to mitigate potential environmental, pathogen, and pest risks associated with movement or release of organisms. Some of these practices are described in more detail in this section due to their importance in precluding adverse impacts from permitting decisions.

1. Types of Application Forms

Individuals applying to receive organisms for importation or interstate movement, or for the distribution of biological control organisms, must select from several U.S. Government forms for their application. These OMB-approved forms are available both online, within the APHIS electronic permitting system, and in the original hard copy formats. In general, the appropriate type of application form is determined by the combination of the material to be moved and its intended use. Guidance regarding how to complete a permit application, including guidance specific to the various information blocks on the application, is available at: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/ct_plantpest. The types of application forms related directly to permitting under 7 CFR part 330 include:

PPQ Form 525A:	Application for Permit to Receive Soil
PPQ Form 526:	Application for Permit to Move Live Plant Pests, Biological Control Organisms, or Noxious Weeds

However, there are a number of other related permits (not covered by the part 330 regulations) that may be required for movement of specific commodities:

PPQ Form 546:	Agreement for Post-entry Quarantine
PPQ Form 585:	Application for Permit to Import Timber or Timber Products
PPQ Form 586:	Application for Permit to Transit Plants and/or Plant Products through the United States
PPQ Form 587:	Application for Permit to Import Plants or Plant Products
PPQ Form 588:	Application for Permit to Import Prohibited Plants or Plant Products for Experimental Purposes
PPQ Form 621:	PPQ 621 - Application for Protected Plant Permit to Engage in the Business of Importing, Exporting or Re- exporting Terrestrial Plants or Plant Products That Are Protected

The PPQ Form 526 application requests movement of live plant pests, biological control organisms, or noxious weeds as the desired organisms. If an organism to be imported is on or in host material, then a separate permit is not required for the host material if that host material is not intended for propagation. However, if the importation of the plant material is for propagation, then at least one of the other applications is needed for the plant material.

Any importation or interstate movement of soil for the purpose of isolating or culturing micro-organisms from the soil requires use of the PPQ Form 526 application. The PPQ Form 525A states that, "If you intend to isolate and/or culture live organisms (such as fungal plant pathogens or nematodes) from the soil, then you must hold a valid plant pest permit based on PPQ Form 526. PPQ Form 525A cannot be used for this purpose." APHIS requires a PPQ Form 525A permit for movement of soil for the purpose of physical and chemical analysis.

This distinction between the coverage of PPQ Form 525A and of PPQ Form 526 permits is important because many plant pests are soil-borne or have life stages that survive in the soil. The movement of soil, therefore, vectors unknown or unidentified organisms. If the intended use of the soil is not likely to perpetuate or increase the pest risk, then the permit conditions reflect this situation. Conversely, if the soil is intended as a medium for the plant pests, and/or if the intended use of the samples encompasses isolating and increasing plant pests, then permit conditions are more restrictive. The pests known to be present in an area also affect the risks inherent in the samples, that is, the origin of the soil is a factor affecting permit conditions.

Other movement permits require consideration of unidentified plant pests on plant material. Just as with the movement of soil, plant pests may be vectored in or on plant parts moved under other types of permits (e.g., PPQ Form 546, PPQ Form 585, PPQ Form 587, and PPQ Form 588); however, the permit conditions for these permits require plant materials to be free of plant pests. While the PPQ Form 587 permit to import plants or plant products primarily focuses on potential pest risks associated with commercial shipments of food as a commodity, the safeguards under 7 CFR §§ 319.56 and 319.37 are designed to reduce pest risk to an acceptable level. Permits to transit (PPQ Form 586) focus on safeguarding against pest risk associated with the security of the packaging. Permits encompassing uses of plants or plant products that are protected (PPQ Form 621) focus on compliance with the Convention on International Trade in Endangered Species requirements (codified at 50 CFR sections 17.12 and 23.23).

2. Exceptions from Permitting

Section 411(c) of the PPA provides an exception from the permitting requirements for the importation or interstate movement of plant pests as identified by the Secretary of Agriculture. Certain indigenous plant pests are distributed throughout the continental United States and are known to either commonly accompany plants or plant products moved in interstate commerce, or are so widespread that additional permit restrictions are unlikely to mitigate existing risks. Although the PPB considered lifting restrictions on these plant pests prior to the PPA of 2000, there was no clear statutory basis that authorized consideration of an exemption. After the PPA provided the authority, APHIS lacked a process to recognize exceptions. Therefore, APHIS is proposing to list regulated organisms that can be moved interstate within the continental United States without further restriction, but will continue to require permits for importation of plant pests. The list will be maintained on the APHIS web site at: http://www.aphis.usda.gov/plant_health/permits/organism/index.shtml.

The proposed wording in 7 CFR § 330.205 references a list of plant pest species that could be moved interstate within the continental United States without restriction. The list would be composed of plant pests from two distinct categories:

- Plant pests that are from field populations or lab cultures derived from field populations of a taxon that is established throughout its entire geographical or ecological range within the continental United States.

- Plant pests that are commercially available and raised under the regulatory purview of other Federal Agencies.

The proposed regulations would include provisions for persons to petition APHIS for the addition of species to, or removal of species from, the list of organisms that could be moved within the continental United States without restriction. Petitioners who request additions to the list must demonstrate that the species belongs to one of the three above categories. Petitioners who request removals from the list must demonstrate the decision that the plant pest belongs to one of categories was in error.

Regarding petitions to add plant pests to the list, if APHIS determines that it is appropriate to allow the suggested organism to be moved within the continental United States without restriction (no permit needed), then a notice would be published in the FR to propose an amendment to the list. Any such notice would be supported by information documenting APHIS' review. A petition template will be maintained on the APHIS web site at: http://www.aphis.usda.gov/plant_health/permits/organism/index.shtml.

APHIS will review the information in each petition for completeness and sufficiency of evidence documenting that the plant pest belongs to one of

the three categories. APHIS reserves the right to add or delete organisms from the list(s) without public comment, but will provide notice of upcoming changes in the FR. APHIS will also use its Stakeholder Registry as another means of notifying the public of proposed actions and requesting comments. To receive notifications via the Stakeholder Registry, sign up at: https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new.

APHIS also reserves the right to add or delete organisms from the list(s) without receiving petitions when a change is based on information internally available to the Agency. APHIS does not intend to evaluate or add genetically modified organisms under this process because those organisms are regulated under 7 CFR 340.

3. Conditions for Packaging and Transport

Regulated plant pest organisms that are transported into, transited through, or moved interstate within the United States must be packaged in a manner that prevents their dissemination prior to receipt at the ultimate destination. Specific permit conditions for packaging and transport supersede all other regulations. These general regulations include the following—

- the packaging is required to consist of at least two containers (one primary (inner) and one secondary (outer) containers); and
- each of the containers must be securely sealed to prevent dissemination of the enclosed organisms or articles.

The primary package/s must contain all organisms and must be constructed and safeguarded in such a way that the packaging remains sealed and structurally intact during transit. Practically speaking, this means that the packages would have to be able to withstand changes in pressure, ambient temperature, and other climatic conditions incidental to transit, as well as routine shock or impact.

Packing material must be free of plant pests, noxious weeds, or associated articles, must either be new, sterilized, or disinfected prior to reuse, and must be suitable for the organism, weed, or article to be transported. Also, APHIS expects any organisms sent from foreign origins by air cargo to meet all requirements of the International Air Transport Association. Guidance regarding suitable outer shipping containers, inner packages, and packaging is provided at: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/ct_plantpest.

Adherence to the above conditions is designed to preclude dissemination of plant pests during transport.

C. Potential Alternatives and Permit Components Not Analyzed in Detail

APHIS considered many suggestions in recent years regarding revisions to the permit processes for movement of plant pests. Some of these are discussed in chapter 1, section A.3. (Introduction to the Purpose and Need) regarding previous efforts to update the regulations. Most recently, comments regarding approaches to regulating plant pests were received by APHIS during the scoping period for this EIS (October 20 to November 19, 2009). APHIS carefully considered these suggestions, and some were incorporated into the preferred alternative. Other suggestions related to regulatory approaches under the comprehensive risk mitigation program alternative. Some commenters expressed preferences or commented on internal review processes rather than potential pest risks or environmental consequences.

Although Agency considerations are designed to include analyses of environmental consequences of all reasonable alternatives and their components, logistical considerations related to available fiscal, facility, and human resources also affect the decision most feasible for Agency implementation. This does not mean that those alternatives and components will not be considered in future reviews; however, they may not be readily applicable for the current level of technology or Agency resources. This section describes additional approaches or components, and the reasons they are not analyzed in detail in this EIS.

One scoping comment suggested that APHIS establish a time limit for issuing release permits for candidate biological control organisms. All permit applications are associated with different pest risks, and submission of basic information by the applicant may not provide the level of detail needed to assess risk for any specific organism.

Members of the Technical Advisory Group for Biological Control Agents of Weeds (TAG) review information on petitions for the first-time release of biological control organisms of weeds, and who make recommendations to APHIS concerning the release of biological control organisms. Members are volunteers from various agencies and organizations. Review time is dependent upon the technical completeness of the petition submitted. Likewise, APHIS consults with the U.S. Department of Interior's Fish and Wildlife Service (FWS) and CBP regarding how best to issue permits in a manner that facilitates compliance and movement of the permitted species. There is ongoing work among these agencies to improve consultation efficiency. The timeframe for review and concurrence from FWS is out of the control of APHIS.

Another comment suggested that additional technical advisory groups be formed for biological control organisms of arthropods and of plant/arthropod pathogens, respectively. Creating additional technical advisory groups to analyze plant/arthropod pathogens is not practical because, historically, there have been very few organisms in these categories, and the costs associated with administering these groups may not be justifiable. While additional technical advisory groups could increase certainty in the process, the product of their review remains only a recommendation to the Agency. TAG recommendations have never been binding and, if the system were altered to unequivocally accept their recommendations, this would effectively deny the decisionmaking authority vested in the Agency.

APHIS continues to receive additional information after a TAG recommendation is received, often in the form of interagency consultations. APHIS is, however, considering an ad hoc group for review of microbial biological control organisms. There is a NAPPO petition process used for arthropods for entomophagous biological control organisms that is similar to the TAG, but there is not yet one for pathogens. Nevertheless, some petitions for entomopathogenic biological control organisms have been reviewed using the same NAPPO petition process (e.g., *Nosema* for gypsy moth control, and a pathogenic nematode for control of *Sirex noctilio*).

In the public scoping comments, a risk-based matrix submitted by USDA–National Institute of Food and Agriculture scientists regarding the environmental release of biological control organisms relies on regulating via notification. In the past, the PPB has never regulated based on notifications. While the risk-based analysis parts of this matrix are inherent in the preferred alternative, each of the proposed matrix categories would require either a list of those organisms that meet the criteria, or an unequivocal description of the organisms that are in the categories. To a limited extent, the preferred alternative implements this approach by creating exceptions and exemptions.

One comment suggested regulating Formosan subterranean termites as plant pests. These invasive, soil-inhabiting pests (with large foraging ranges) pose threats to structures, and are regulated as pests of plant products. USDA–ARS operates a domestic suppression program focusing on the use of available control methods. Creating a specific risk-based permitting program for these infrequently requested pests would not be an effective use of program funds because the current permitting system appears capable of analyzing and inspecting the facilities associated with these applications.

Another comment requested that pathogens of bumble bees be regulated as plant pests. Bumble bee parasites were construed as indirect plant pests, but are now recognized as diseases or parasites of concern to the United States. Their importation is regulated by APHIS. Independent of the proposed revisions, APHIS is currently evaluating the feasibility of regulating the interstate movement of bumble bees, and possibly developing a domestic clean stock program for them. APHIS has started revising the bee regulations, found in 7 CFR 322.

One scoping comment suggested the adoption of novel mitigation procedures to facilitate the release of candidate biological control organisms. In particular, the commenter cited the use of parthenogenetic reproduction (unmated females of some insect species only produce male offspring) and the use of SIT to achieve temporary and reversible release of the candidate organisms. Each of these technologies is at various stages of development for use with certain species. Their application for use in the mitigation of biological control organisms depends upon unequivocal evidence that these methods will be effective. The pest risk considerations make it critical that APHIS only approves techniques that will eliminate the potential risks. For example, there must be a method to ensure that only unmated females are used for parthenogenesis. For F_1 sterile insect technique, the irradiation must ensure sterility to the point at which any lingering population will readily collapse after the release is completed. This approach may work well in an eradication program where the time and effort can be taken to develop effective techniques to reduce the pest population. Effective application of this technology in a biological control setting to readily mitigate risks, however, has not conclusively been demonstrated. These technologies eventually may be considered for mitigation of pest risk associated with releases of biological control organisms, but only after their development and application is conclusively demonstrated.

Acknowledging that EPA-registered products are exempt, one comment expressed concern over the regulation of ". . . dozens of non-registered microbes/biological mixes shipped around the" United States. In addition to EPA-registered products, non-registered microbial pesticides that are transferred, sold, or distributed, in accordance with 40 CFR 152.30, will not be regulated under 7 CFR Part 330. However, many microbial species, (e.g. *Bacillus subtilis*), have both pesticidal and non-pesticidal strains; some strains have both pesticidal and non-pesticidal attributes. Those not overseen by EPA as pesticides via pesticide registration, pesticide experimental use permit, or via 40 CFR 152.30 are, therefore, not exempt from 7 CFR part 330 on the basis that they are adequately regulated by EPA. If these mixes contain organisms that are not pests of plants or plant products, then APHIS lacks jurisdiction over the organisms.

Currently, applicants can receive a "letter of no jurisdiction" for their future use when their permit application involves the movement of an organism or mix that lacks pests of plants or plant products. Under the current 7 CFR § 330.207, APHIS inspectors recognize permits issued by other Federal agencies; therefore, additional APHIS permitting is not required. For example, it is possible that after years of movement under PPQ Form 526 permits and years of supporting data, the permit holder may consider submissions to EPA for product registration. Further, the PPB routinely issues permits for microbial biological control organisms during the early phases of development, such as laboratory studies, controlled environment research, and small-scale field release. Field releases restricted to less than 10 acres usually are conducted under a PPQ Form 526 permit, rather than the more extensive and more costly EPA-issued experimental use permit or registration. Full-scale release as an EPA-registered product usually is preceded by APHIS analyses, permits, and consultation. Finally, ubiquitous plant pests may present such an exceedingly low pest risk that they do not justify the costs associated with continued Agency scrutiny and regulation. This is the basis for one of the criteria that would be used to recognize an exception from permitting under the preferred option.

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III. Affected Environment

The affected environment includes any location where the containment or movement of soil, plant pests, noxious weeds, or biological control organisms could have an effect. In theory, the geographic area potentially affected by the movement of biological control organisms, weeds, and plant pests could include parts of all 50 States and all territories of the United States. However, the effects of releases of these organisms are restricted by climate, host plants, and other range-limiting factors. For all practical purposes, direct effects to certain habitats, (e.g., marine, estuarine, tundra, and alpine areas) from movement and containment of these organisms are virtually nonexistent because the PPB rarely issues permits for plant pests in these habitats. Indirect and temporary effects (such as soil erosion) may affect marine and estuarine environments, however, this is not expected to be substantial given the limited host range of most permitted organisms.

Potential effects to the global commons are expected to be minimal in that the limited transport of soil and these organisms is not expected to contribute substantially to greenhouse gas production or affect global climate change or other natural atmospheric stabilizing processes. Most biological control organisms released into new areas have not acclimated readily or resulted in any measurable effect on the target organism or other potential hosts present. It was estimated that only 1 to 2 percent of all introductions resulted in environmental or related problems (Suckling and Sforza, 2014; Hokannen et al., 2003; Pimentel et al., 1989). The percentage of introduced arthropods that are successfully established for the purposes of weed control is about 65 percent; however, the comparable percentage for those arthropods introduced for the purpose of insect biological control only ranges from 25 to 34 percent (van Lenteren, 2003). As is evident, only a small number of these introduced organisms resulted in adverse or unanticipated outcomes.

Barring an accident in transport, the movement to and from secure biocontainment facilities should have no effects on the natural environment other than the noise and emissions of exhaust from vehicular transport. Environmental impacts from vehicular accidents are subject to emergency response, rather than risk assessment, and their effects cannot be accurately assessed outside of site- and condition-specific circumstances. (Issues related to the method of movement are discussed in the following section of this chapter.)

Biocontainment facilities may be geographically situated to avoid introductions into the surrounding areas by avoiding the rearing of organisms that have hosts in the general vicinity of the facility, or by using facilities where the weather is not conducive to introduction. In the event

of the inadvertent release of an organism, a lack of nearby hosts prevents establishment of the organism from occurring. (Issues related to the containment and biocontainment facilities are discussed in greater detail in chapter 3.B.)

Potential effects from plant pests (e.g., deforestation or eradication of hosts) are possible for some organisms, but are not anticipated when applying any of the alternatives. Based on the permit applications submitted in recent years, it can be expected that most effects will be localized near agricultural fields or forested areas, and pose impacts limited to the target host species. The level of control of the target host/s will depend upon the specificity, numbers released, and ability to adapt to local conditions at the site of release. Barring any unforeseen adaptation or unlikely host preference for an untested species, adherence to permit conditions would not be expected to result in measurable adverse environmental consequences. Permits for release are issued with the understanding that the organism in question may become established, and then spread naturally or spread through human-assisted movement. The maximum potential geographic spread, based upon host distribution, must be assumed unless there are mitigating factors related to climate, conditions that naturally restrict spread (e.g., island effects), unique characteristics of the biological organism, or unique characteristics of the host/s. It should be recognized that there are always some uncertainties when dealing with regulation of movement of a biological organism and, therefore, the current decisions must be based upon thorough review of the organism prior to making a conservative determination to issue or deny a permit application. The ability to adapt is an important consideration, particularly for micro-organisms and arthropod species.

The PPB focuses on pest risk in its review of permit applications. PPQ Form 526 applications involve the movement of live organisms that require certain conditions for their survival or maintenance. The researchers working with these organisms are generally concerned with the availability of pure strains of viable organisms to meet their testing requirements. Therefore, the permit conditions are designed to ensure movement or maintenance of their organisms in a manner that precludes pathogen and pest risks. Other than those viruses and spore-forming organisms which can tolerate environmental conditions that are anoxic (low oxygen), extremely cold, extremely hot, or extremely dry, most permit applications are for organisms with a more limited range of conditions favorable to their survival and growth. Review of a given application may result in permit conditions that make allowance for survival of the organism while still maintaining the requisite exclusion of pest risk. This aspect of the micro-environment related to movement and facilities is discussed briefly in the sections below on issues related to the method of movement and containment. There is no attempt to discuss all

possible environmental conditions required for organisms requested by applicants for permitting; however, this section is designed to give the reader an indication of the relative flexibility provided in the regulations for analysts' decisions regarding the issuance of permits.

A. Issues Related to Method of Movement

The potential release of biological control organisms during transport should be precluded prior to receipt at the ultimate destination. The packaging requirements proposed for the preferred alternative are consistent for all modes of transportation; these were described in chapter 2.B., Component Methods of the Preferred Alternative, subsection 3, Conditions for Packing and Transport. These requirements would apply to all biological control organisms that require a permit.

The movement to and from secure biocontainment facilities should have no effects on the natural environment other than the noise and emissions of exhaust from vehicular transport. The packaging for organisms, soil, and associated articles is designed to preclude release of pests. Environmental impacts from vehicular accidents are subject to emergency response, and the relative risk of an accident resulting in the escape of a permitted organism is less likely for some modes of transportation than others.

Hand-carry of organisms by the applicant in approved packaging serves to ensure the materials are closely protected, and arrive securely at their destination intact. Transportation by air freight may be insured, but this does not preclude rough handling or damage to the packaging. Likewise, ship or rail transport on freight or manifest lists may not be handled with care. The applicant who has a permit to move living organisms is more likely to use modes of transportation (e.g., air transport) that can ensure the viability of the organisms upon arrival at the destination because of the shorter transit time. The condition of the organisms at the destination is often time-sensitive because of the relative lack of available nutrition and water while sealed in a suitable primary container. The statistical likelihood of an accident using these public modes of transportation is less than the likelihood of a motor vehicle accident (Noland, 2013; Savage, 2013); however, there may be more control over the handling and loading of packaging transported by motor vehicle. The likelihood of survival of organisms transported under permit could be substantially reduced in catastrophic accidents, such as a plane crash. The packaging requirements make it likely that the primary and secondary containers would not be ruptured by rough handling, but it is less clear how well the contents would be secured in the event of an accident. Even though there is low likelihood that unintentional release will result in environmental impacts (Hokkanen et al., 2003; Pimental et al., 1989), proposed packaging and

transport requirements are designed to preclude potential introductions to natural environments.

B, Issues Related to Containment

Containment conditions for regulated organisms vary with their associated pest risk potential. When biological organisms are moved from one region to another, safeguards are needed to prevent unintended adverse consequences to agriculture and the environment. If the regulated article being transported is not known to be present in the new destination, the regulated article needs to be adequately contained to prevent dissemination into the environment. Sometimes the primary regulated article being moved may be widespread at the new destination; however, the regulated article may have associated with it other biological organisms of concern to agriculture. For example, arthropods may carry with them diseases (pathogens) or parasitoids that may be of concern to agriculture; in these cases, containment must be stringent enough to prevent the dissemination of these secondary agents of agricultural risk. Biological control organisms that have not been approved for environmental release at the destination site are subject to containment.

Containment may be achieved by a combination of standard operating procedures for handling the articles/organisms, appropriate equipment, and secure physical features in the facilities housing the regulated articles. In some cases, less than optimal physical containment features may be mitigated by good handling procedures. When making containment recommendations, APHIS considers how handling procedures will complement physical facility features to ensure containment of the regulated organism. Proper disposal of biological wastes and devitalization of all materials in direct contact with regulated organisms are considered to be critical to adequate containment. Proper training of all individuals handling regulated organisms is also considered critical to containment.

Conditions for use of plant pathogens might require that all handling of these organisms occur in a certified biosafety cabinet. APHIS requires yearly professional certification of these cabinets. All biological waste and packaging that is in contact with the regulated article must be adequately treated, (usually by autoclaving, incineration, prolonged freezing (e.g., insects), or sterilization with bleach or alcohol) prior to disposal as garbage or trash. If the regulated article can be dispersed aerially (e.g., fungal spores, or alate (winged) insects), APHIS requires appropriately sized mesh screens be placed over air vents that will trap the regulated article, in addition to adequate primary containment (cages, sealed petri dishes, etc.). HEPA filtration may be required in exhaust air vents if the regulated article is of microscopic size and is capable of

becoming aerially dispersed. In some cases, negative air pressure is required to be maintained in the containment areas so that air flow is always from the outside into the containment area.

Vestibules with interlocking doors may be required to isolate primary containment areas from the outside. If the regulated article is water-borne, appropriately sized traps are required to be placed on sink drains. If necessary, all waste water may need to be collected in a trap and devitalized before disposal into the general sewage system. As the last person with control of the organism, the permit holder is held responsible for devitalization prior to potentially infested materials entering the waste stream. APHIS also considers the ability of regulated articles to establish themselves in different geographic/climatic areas when evaluating containment requirements for any given plant pest. For example, tropical butterflies moved into a temperate area of the United States where there are no known hosts for the insects may require less stringent containment than the same butterflies moved to a tropical/subtropical part of the country where they are not established.

During the permit application process, APHIS may require applicants to provide standard operating procedures that describe how the applicant intends to prevent dissemination of the regulated articles. These standard operating procedures are evaluated by APHIS, and a physical inspection of the premises may be conducted before a permit is issued. APHIS permit conditions require that the standard operating procedures be followed at all times, and that the facilities are maintained in the same condition throughout the life of the permit. Guidelines for containment of regulated organisms and inspection guidelines can be found on the APHIS web site at: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/sa_containment/ct_containment_facility_inspections.

APHIS may inspect any facility holding an APHIS permit during normal business hours to ensure permit compliance.

C. Issues Related to Spread Following Release

The movement of organisms beyond their natural range has been likened to a game of biological roulette (OTA, 1993). Once in a new environment, a species may die out or may survive and reproduce. A species is described as an invader when it colonizes and persists in an ecosystem where it has never been before (Mooney and Drake, 1989). Some invaders may produce little effect on the environment, but others may spread unimpeded, resulting in major environmental and economic impacts. The introduction of a nonindigenous species into the environment

may be intentional and beneficial, such as the introduction of classical biological control organisms, or accidental and undesirable, such as pest species that enter with commodities imported into the United States from other parts of the world. The invasion of ecosystems by nonindigenous organisms is an increasing problem in the United States. Even organisms whose release into the environment is initially considered beneficial may have unexpected or adverse impacts. Negative effects of invasions are usually categorized as: (1) colonizing species that become a pest, or (2) colonizing species that lead to an extinction of native species (van Lenteren, 2003).

Although many nonindigenous species are introduced into the United States through a variety of pathways, only a small proportion of those species actually establish. An estimated 5 percent of introduced species established in the Eastern Hemisphere (di Castri, 1989). Whether an introduced species spreads and produces adverse environmental or economic impacts depends on many factors, such as genetic variability, reproductive capability, ability to disperse, and ability to survive on many hosts (van Lenteren, 2003). A species that invades but does not spread is unlikely to become as serious a problem as an invader that rapidly expands its range. Spread from the point of release may occur by human movement, by natural dissemination, or both.

Natural dissemination can occur when there are no geographical barriers to block the movement of species through wind, rain, and wildlife dispersal, and by natural disasters, such as hurricanes or floods, which may carry species farther than expected. Continued spread of an established population often occurs because of adaptations for dispersal (Sakai et al., 2001). Although natural spread is an important mechanism for spread of invasive species, a significant number of invasive species spread throughout the United States via pathways associated with human activities (OTA, 1993). These transport pathways include ballast water; bait species; commercially sold species; horticultural/agricultural uses; smuggling; transport on vehicles or other inanimate objects; contaminants in shipments of seed, plants, fish, or wildlife; and biological control (OTA, 1993).

1. Spread from Intentional Releases

Some intentional releases of plants that resulted in unintended consequences include infestations of the invasive weeds purple loosestrife (*Lythrum salicaria*), scotch broom (*Cytisus scoparius*), and water hyacinth (*Eichhornia crassipes*). These invasions occurred as a result of ornamental plantings in ponds and gardens (Penfound and Earle, 1948; Blossey et al., 2001; Zouhar, 2005). Grass species, such as Bermuda grass (*Cynodon* spp.), kikuyu grass (*Pennisetum clandestinum*), and fountain grass (*Pennisetum setaceum*) quickly spread outside the confines of gardens and lawns, and can invade nearby wildlands (Mears, 1970;

USDA-NRCS, 2000; Poulin et al., 2005). The invasive plants kudzu (*Pueraria lobata*) and saltcedar (*Tamarix* spp.) were first imported to reduce soil erosion; however, now they are widespread in natural areas causing adverse environmental impacts (Di Tomaso, 1998; Everest et al., 1999).

Once established, invasive plants can spread by seed or vegetatively. Seeds can be carried by wind, fire, water, or animals, and can be carried on the shoes of hikers, vehicle tires, boats and boat trailers, and in the intestines of animals. Some invasive plants also have the ability to reproduce vegetatively by sending out underground shoots that form new plants.

Unlike releases of pest species that are considered detrimental to the environment, intentional releases of classical biological control organisms are expected to establish and spread in the environment, causing beneficial effects by reducing the impact of another undesirable invasive species.

Establishment of biological control organisms in a novel habitat depends on several factors, including climate suitability and the presence of alternate hosts/prey (Boivin et al., 2006). For species introduced for insect biological control, only 25 to 34 percent of introduced arthropod species established (van Lenteren, 2003). For biological control of weeds, establishment of natural enemies is estimated at 65 percent (Crawley, 1986), although establishment of these species does not guarantee control of the target weed.

In certain cases, releases of classical biological control organisms of arthropod and weed pests resulted in unintended effects to nontarget species. For example, the European tachinid fly, *Compsilura concinnata*, introduced into North America in 1910 for control of the gypsy moth (*Lymantria dispar* L.) caused regional declines of native giant silk moths because of heavy parasitism of larvae (Boettner et al., 2000). Organisms released for biological control may also spread to unexpected locations. For example, the biological control organism, *Cactoblastis cactorum*, was purposely introduced into the West Indies to control prickly pear cactus but spread northward to Florida, possibly in infested plant material, and now threatens the native prickly pear cactus throughout its range in the United States. A rust disease, *Puccinia cardorum*, of nodding thistle (*Carduus nutans*) was permitted in 1997 for a limited release in Virginia; by 1999, it spread naturally to California and Nevada.

2. Spread from Unintentional Release

There are many examples of invasive species unintentionally entering the United States via human transport (OTA, 1993). Expanded global travel and commerce led to increases in the establishment of invasive species. Within the United States, increased interstate transport, trade, and travel

can rapidly distribute a new invader throughout the country. Wood pests (e.g., Asian longhorned beetle (*Anoplophora glabripennis*) and the emerald ash borer (*Agrilus planipennis*)) hitchhiked into the United States in wood packing material from Asia, and then were inadvertently transported within the United States in wood products, such as infested firewood, nursery stock, and logs. Agricultural crops can become contaminated with seeds from invasive plants. Agricultural produce shipped interstate may harbor nonindigenous pests. For example, some of the infestations of Mediterranean fruit flies (*Ceratitis capitata*) in California resulted from the movement of infested tropical produce shipped via mail from Hawaii. Invasive insect species, such as the European gypsy moth (*Lymantria dispar*), can cling to vehicles and other objects that are transported across State lines. Japanese beetles (*Popillia japonica*) can be transported to new areas via cargo planes. Imported fire ants (*Solenopsis* spp.) may be transported in root balls of nursery stock, in soil attached to vehicles, and other materials.

New species can also be introduced through the exotic pet trade. Fish tanks and aquariums that contain nonnative vegetation and fish are often dumped into storm drains, lakes, and ponds when their owners can no longer care for them. Some invasive species thought to have spread this way are the plants giant salvinia (*Salvinia molesta*), and hydrilla (*Hydrilla verticillata*), and the snakehead fish (*Channa argus*).

3. Environmental and Economic Impacts of Invasive Species

The annual cost to the U.S. economy from the approximately 50,000 nonindigenous species in the United States was estimated at $120 billion per year (Pimental et al., 2005). Although many species are negatively affected, estimating the full extent of environmental damage caused by nonindigenous, invasive species is difficult (Pimental et al., 2000). Invasive species contributed directly to the decline of 42 percent of the threatened and endangered species in the United States (TNC, 2010). Invasive species are either a primary or secondary threat to 58 percent of federally listed insects in the United States (Wagner and Van Driesche, 2010). Other adverse impacts caused by nonindigenous invasive species include declines in native species, reduced biodiversity, and transformation of ecological communities and ecosystems (OTA, 1993).

It is important that APHIS ensure adequate restrictions on movement, containment, and release of nonindigenous plant pests and biological control organisms imported into the United States, and moved interstate under authorization because of the potential harmful effects that invasive species can cause. These restrictions are key in contributing to the prevention of the unwanted introduction and spread of invasive species in the environment. Although spread of a given organism is dependent on its hosts' ranges, impacts of invasive species affect other organisms that use

or depend upon the host species for food or survival, and may indirectly affect many additional species.

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IV. Environmental Consequences

This chapter of this EIS is divided into sections discussing the overall benefits and risks of various permitting decisions, a comparison of potential environmental impacts from permitting alternatives, and a discussion of permit process considerations related to specific issues.

A. Overall Benefits and Risks

The overall benefits and risks of various permitting decisions are discussed briefly in this section. This provides a background for the types of impacts that are compared for each permitting alternative in the following section.

1. Containment Permit Issues

APHIS evaluates potential biocontainment facilities for an organism requiring containment before a permit is issued. As part of the facility evaluation process, APHIS evaluates standard operating procedures supplied by the applicant to ensure proper handling of the regulated organisms. When needed, APHIS assists applicants in the development of adequate standard operating procedures. APHIS' facility evaluations ensure that the physical structure is constructed and maintained to contain permitted organisms. APHIS' evaluations may include a site inspection before a permit is issued. In addition, all facilities holding APHIS permits may be inspected at any time during normal business hours throughout the life of the permit to ensure that permit conditions and facility requirements are being adhered to, as agreed upon before permit issuance. Inspections by APHIS may be unannounced, that is, not previously scheduled with the permit holder. Guidelines to containment of plant pests are published on the APHIS web site at: https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/sa_containment/ct_containment_facility_inspections.

These guidelines allow potential permit holders to design facilities that will contain the requested organisms.

a. Benefits

Adequate containment of plant pests allows for increased research, diagnostic, and educational opportunities that otherwise might not occur. This research within biocontainment facilities facilitates the development of basic scientific knowledge, and any subsequent applications resulting from that work. Research regarding quarantine-significant pests within a biocontainment facility may help find solutions to eradicate the pest. In many cases, research with significant plant pests provides insight into how to make plants resistant to the pest and, in doing so, benefits U.S.

agriculture. Allowing potential and known plant pests to be held and studied in a biocontainment facility increases the knowledge base that could have important ramifications for agriculture, both in terms of scientific knowledge acquired, and increased public awareness. Potential biological control organisms may also be safely tested in biocontainment facilities to assess their potential for efficacy without releasing them into the field.

Diagnostic work in contained facilities assures containment of pests that may not already be present in an area. These laboratories often need reference cultures or organisms to be available for comparisons that allow identification of the unknown organisms. In these situations, host-specificity testing within biocontainment facilities becomes a way to identify the host range of specific strains, and compare symptomatology to known strains.

Host-specificity testing within biocontainment facilities also can be used to determine the potential plants affected by a pest or biocontrol organism prior to any movement to the environment. Results of this testing provide information about potential adverse impacts from such movement. If adverse impacts could not be mitigated by permit conditions, then environmental releases would not be authorized.

Allowing plant pests to be used in contained educational/display facilities increases public awareness of plant pests and the role of these organisms in agriculture. Permits for educational purposes authorizing use within biocontainment facilities allow USDA personnel and diagnosticians in private industry to have continuing education opportunities that enhance emergency preparedness in advance of an outbreak, such as recent soybean rust and thousand cankers of black walnut disease identification training.

b. Risks

The primary risks relate to the lack of adherence to conditions for movement or holding of the regulated organisms or articles by a permittee. If the permittee does not maintain the facility in the condition as agreed upon with APHIS, there is the potential for plant pests to be inadvertently released into the environment. In such cases, APHIS may revoke the permit. This may require destruction of all plant pests authorized for movement under the permit. APHIS believes that sufficient safeguards (e.g., facility evaluations, onsite inspections) are in place to allow permit holders to receive and work with specific regulated organisms in an APHIS-evaluated facility without posing risks of release or of potential adverse effects. Lack of compliance by the permit holder, natural disasters, and accidents subject the surrounding environment to potential

increased risk of introduction of undesirable pests and unacceptable environmental effects. Therefore, APHIS reviews facility compliance and permit conditions very carefully before issuing permits for plant pests.

2. Biological Control Permit Applications

Classical biological control is usually defined as the importation and release of exotic organisms with the expectation that these organisms will establish and reduce the target pest to a lower population level than would occur in the absence of the biological control organisms. Biological control practitioners often argued these introductions are associated with fewer and less detrimental impacts than other control methods, particularly as problems with synthetic insecticides arose (DeBach and Rosen, 1991). Biological control has been viewed as an ecologically benign replacement technology for pest management (DeBach and Rosen, 1991). However, as reports emerged of introduced biological control organisms attacking species other than their intended targets, increased concerns were raised regarding the safety of this strategy. Greathead (1995) indicates more than 5,500 introductions of species were released for biological control worldwide. There is a great deal of literature regarding the benefits and risks of introducing these organisms into the environment (e.g., Howarth, 1983; Greathead, 1995; Simberloff and Stiling, 1996; Cory and Myers, 2000; Follett and Duan, 2000; Louda et al., 2003b; Hoddle, 2004; Louda and Stiling, 2004; Culliney, 2005; van Lenteren et al., 2006a).

a. Benefits

Hoddle (2002) states that benefits of biological control include reduced ongoing expenditure for pesticides, labor, specialized equipment and, potentially, a return to ecological conditions before the arrival of the target pest. Greathead (1995) indicates that impacts of introduced biological control organisms are generally restricted to the target pest, and have minimal effects on nontargets and humans. According to Culliney (2005), biological control of weeds is particularly suited for managing widespread plant invasions in ecologically fragile or low-value habitats (e.g., rangeland and many aquatic systems) because biological control organisms establish self-perpetuating populations and distribute themselves throughout the target's range, including areas difficult or impossible to access by humans. When effective, biological control of weeds is permanent, nonpolluting, energy efficient, environmentally sustainable, and inexpensive compared to other methods (McFadyen, 1998; Culliney, 2005). Other benefits may include increased revenue from improved lands (Anderson et al., 2003), decreased health risks from exposure to weed allergens or toxic chemicals, compatibility with other management practices, and increased biodiversity (McEvoy and Coombs, 2000; Coombs et al., 2004; Culliney, 2005). Examples of successful uses of biological control organisms include the beetle, *Cyrtobagous singularis*, for control of the floating fern, *Salvinia molesta*, in Australia (Room et al.,

1981); the flea beetle, *Agasicles hygrophila*, for alligatorweed control in the United States (Spencer and Coulson, 1976); and *Anagyrus kamali* Moursi and *Cryptolaemus montrouzieri* to control the pink hibiscus mealybug, *Maconellicoccus hirsutus*, in the Caribbean (Kairo et al., 2000).

An exotic organism released for biological control may serve as food for other organisms (van Lenteren et al., 2006a). For example, migratory birds inhabit riparian habitats which contain the nonnative plant saltcedar (*Tamarix spp.*). There is some evidence that the invertebrate community associated with saltcedar (including the exotic leafhopper *Opsius stactogalus* and the saltcedar leaf beetle *Diorhabda* spp.) may directly contribute to the nutritional resources of passerine foraging birds, such as warblers, flycatchers, and vireos (DeLoach and Tracy, 1997). Nonnative leafhoppers specific to saltcedar are fed upon by insectivorous birds and augment the diet of Lucy's warbler (*Vermivora luciae*) (Yard et al., 2004). Numbers and species richness of passerine birds were significantly greater in the presence of the saltcedar leaf beetle (*Diorhabda* spp.) than in their absence (Longland et al., 2006).

b. Risks

Greathead (1995) states that direct effects, such as damage to nontarget organisms, are the most serious potential risks from the introduction of exotic biological control organisms. Host specificity of introduced organisms and the possibility of host shifts to nontarget species are at the center of debate regarding releases of nonindigenous biological control organisms (Ehler, 2000). Once a biological control organism is released into the environment and becomes established, there is a possibility it could move from the target to attack nontarget hosts. Native species that are closely related to the target species are the most likely to be attacked (Louda et al., 2003b), yet host shifts by introduced weed biological control organisms to unrelated plants are rare (Pemberton, 2000). However, Secord and Kareiva (1996) indicate that there are at least 20 cases of host shifts among biological control organisms documented in scientific literature. Releasing multiple organisms in a search for the one that successfully controls the target increases the probability of attacks on nontarget native species (Strong and Pemberton, 2000). If nontarget species are attacked, the resulting effects could be environmental impacts that may not be easily reversed.

Suckling and Sforza (2014) reviewed the literature and completed an analysis on 512 biological control agents of plants released in over 75 countries. Of the 512 agents, 91.6 percent showed no known adverse long-term impact on nontarget plant populations. When impacts were described, 39 (7.6 percent) of agents had minimal or minor impacts that resulted in no individual plant mortality or reduction in reproduction.

Four of the 512 agents (0.08 percent) resulted in severe impacts that included nontarget plant mortality prior to reproducing which resulted in the decline in the species abundance. These severe impacts occurred in the plant families Asteraceae and Cactaceae. Of 140 cases of nontarget plant impact, 108 (77 percent) cases of recorded nontarget impacts were in the same plant family as the target weed, and 54 percent were in the same genus as the target. Suckling and Sforza (2014) discuss the four biological control organisms in the genera *Cactoblastis*, *Rhinocyllus*, *Larinus*, and *Trichosirocalus* that were responsible for these impacts. The largest direct impacts were from *Cactoblastis cactorum* on native cacti and *Rhinocyllus conicus* on native thistles, but these introductions would not be permitted under today's standards (Suckling and Sforza, 2014). *Cactoblastis cactorum* has never been permitted in the United States.

Biological control organisms generally spread without human intervention. In principle, therefore, release of the biological control organism, at even one site, should be considered equivalent to release over the entire area in which potential hosts occur, and in which the climate is suitable for reproduction and survival. Ecological effects of introduced biological control organisms cannot be predicted with certainty, and forecasting the impacts of these releases is an imprecise process (Simberloff and Stiling, 1996). Hawkins and Marino (1997) concluded that 16 percent (51 of 313) of parasitoid species introduced for biological control in North America have been reported on nontarget, native insects. For example, the European tachinid fly, *Compsilura concinata*, introduced into North America in 1910 for control of the gypsy moth, caused regional declines of native giant silk moths because of heavy parasitism of larvae (Boettner et al., 2000). In addition, Hawkins and Marino (1997) found 11 percent of parasitoids did not establish on their targets and have been recorded from native insects. Direct nontarget impacts causing substantial mortality have not been reported from the release of microbial insecticides or weed pathogens (Barratt et al., 2006).

Introduced biological control organisms may not be successful at reducing the target population in the area of release. Approximately 12 percent of all parasitoid introductions worldwide have led to significant sustained control of the target pests; however, most introductions did not control the pest (Greathead and Greathead, 1992). This is either because introduction did not lead to establishment or establishment did not lead to control (Lane et al., 1999). Worldwide, biological weed control programs have had an overall success rate of 33 percent; success rates have been considerably higher for programs in individual countries (Culliney, 2005). Actual impacts on target populations will not be known until after release occurs and post-release monitoring is conducted. Thorough environmental risk evaluations have been conducted for weed biological control organisms; however, potential risks of biological control organisms for arthropod

control are not as thoroughly studied in prerelease evaluations (van Lenteren et al., 2006a). Several authors suggest that the phylogenetic approach (based on taxonomic relatedness) used for evaluation of weed biological control programs is not sufficient in arthropod biological control for many reasons, including poor knowledge of arthropod phylogeny, the large number of taxa that can be attacked by natural enemies, natural enemies responding to both hosts and host plants, and the inability to culture test species in the laboratory (van Lenteren et al., 2006a; Kuhlmann et al., 2006).

In addition to direct effects of attack of nontarget species and failure of the organism to control the target pest, there are a variety of indirect concerns regarding environmental release of biological control organisms. Indirect effects are the effects of one species on another, mediated by at least one intermediate species, and may influence the performance of released biological control organisms. Indirect effects include contamination, adaptation, interference, competition, and hybridization which can affect the performance of released organisms and human health. These are discussed below.

Shipments of biological control organisms collected from foreign countries may be contaminated with their own natural enemies (e.g., parasitoids, hyperparasitoids), pathogenic and/or nonpathogenic micro-organsims, or with similar looking species that could be mistaken for the biological control organism (Greathead, 1995; Goettel and Inglis, 2006). These contaminants may decrease the efficacy of the introduced organism, or may have an adverse effect on the environment or plant or animal health. Field-collected materials have a much higher potential for harboring unknown contaminants than insectary-reared organisms (Goettel and Inglis, 2006). For example, the seed-head fly, *Chaetorellia succinea* (*C. succinea*), was apparently accidentally introduced into Oregon from a shipment of seed heads that contained an undetected mixture of similar *Chaetorellia* species, including the intended yellow starthistle biological control organism, *Chaetorellia australis* (Balciunas and Villegas, 1999). Since its accidental release, *C. succinea* spread rapidly and attacked safflower, an important California crop, although the risk to the crop appears to be minimal (Balciunas and Villegas, 2001). Screening to ensure field-collected shipments are free of contaminants, as well as inspection of shipments in quarantine with destruction of contaminated or suspect material, can significantly reduce or eliminate this problem.

Introduced biological control organisms may compete with native species that exploit the same resource (Simberloff and Stiling, 1996; van Lenteren et al., 2006a). For instance, the exotic seven-spotted ladybeetle (*Coccinella septempunctata*) and the multi-colored Asian ladybeetle (*Harmonia axyridis*), both introduced for biological control of aphids,

were implicated in an overall reduction in native coccinellids (e.g., Koch, 2003; Finlayson et al., 2008; Elliott et al., 1996). In addition, introducing multiple biological control organisms to control pest herbivores may result in antagonistic interactions (predation and cannibalism) that reduce the effectiveness of those organisms to lower pest populations (Denno and Finke, 2006). Complex trophic interactions (observed as indirect effects to native species) are difficult to predict, particularly when based on studies conducted in quarantine laboratories.

Interference between biological control organisms of insects and weeds occurs occasionally (Greathead, 1995). Other conflicts may occur over the status of targets for control, such as strawberry guava (*Psidium* spp.), which is considered an invasive weed in Hawaii, but is used by residents for its fruit. Another example is saltcedar (*Tamarix* spp.) which is invasive in riparian habitats throughout the Western United States, but is considered nesting habitat for numerous species of breeding and migrating birds (Sogge et al., 2008; van Riper et al., 2008).

Hybridization between the organism and released biotypes of the same or closely related species may result in changed ecological preferences (van Lenteren et al., 2006a). Interbreeding between species used in biological control and native species may change fitness or result in evolution, altering abundance (Hopper et al., 2006). However, Hopper et al. (2006) concluded that there is small risk of large impacts from interbreeding between native species and species introduced for biological control, although more data is needed on the likelihood and impact of interbreeding.

Host-specific biological control organisms that establish but fail to reduce the density of their target host will maintain high populations, providing a food source for native consumers. This provides a food subsidy to native consumers causing large population increases of those species. It could result in significant indirect impacts that exceed the direct effects on nontarget species caused by host shifting (Pearson and Callaway, 2003). An example of this is the environmental release of two species of gall flies (*Urophora affinis* and *U. quadrifasciata*) in the 1970s for control of knapweeds. These host-specific insects failed to reduce populations of their host plants and, consequently, both the insects and the weeds remain abundant. The gall fly larvae provide a plentiful food source for the deer mouse (*Peromyscus maniculatus*), and resulted in a two- to threefold increase in deer mouse populations in knapweed-invaded grasslands. Deer mice compete with other small mammals, may reduce recruitment of native plant populations from increased seed consumption, and may affect vertebrate predators of the mouse.

Introduced biological control organisms can create unintended and unpredictable consequences on human or animal health. Some people develop an allergic rhinoconjunctivitis to the exotic lady beetle, *Harmonia axyridis,* introduced for aphid control, and the beetle is reported to bite humans (Koch, 2003). This beetle is an annoyance to humans by forming aggregations at overwintering sites, often inside homes (Koch, 2003).

Another example of an unpredicted, indirect human health consequence arose from the introduction of the two biological control organisms, *Urophora affinis* and *U. quadrifasciata*, for knapweed control causing elevation of the disease, Sin Nombre hantavirus, by providing a food source to deer mouse populations (Pearson and Callaway, 2006). The deer mouse is the primary reservoir for this virus, and increased densities of hantavirus-infected mice may increase the likelihood of infection in humans (Pearson and Callaway, 2006). A sawfly native to Australia was proposed for biological control of melaleuca in Florida; however, because the larva produces a chemical potentially toxic to cattle and other vertebrates, the release permit application was withdrawn (USDA–APHIS, 2002). Some generalist microbial pathogens are infectious to both vertebrates and invertebrates.

There are few documented examples of adverse effects to nontarget species. This may be the result of insufficient monitoring after an organism is released into the environment. Information on post-release impacts often is quite minimal. With insufficient monitoring, negative impacts (e.g., extinctions or disruptions of community or ecosystem processes) are unlikely to be observed (Simberloff and Stiling, 1996). Less than 1 percent of releases of biological control introductions of insects are known to have caused population-level effects on nontarget species, and only 3 to 5 percent are known to have caused some smaller effects; however, very few introductions included a careful evaluation of nontarget impacts (van Lenteren et al., 2006a). Absence of evidence due to lack of monitoring should not be taken as evidence of absence of nontarget impacts (Stiling and Simberloff, 2000). Post-release monitoring benefits regulators because it validates prerelease predictions and informs future decisions; unfortunately, there is often no funding for this research and no ability to require or oversee post-release monitoring (Barratt et al., 2006). A USDA–ARS policy requires researchers to monitor nontarget effects of introduced biological control organisms: the implementation and extent of monitoring varies across programs (Barratt et al., 2006).

c. Balancing Risks and Benefits

Balancing the risks and benefits is the final step in the decisionmaking process of whether to permit the initial introduction of an exotic biological control organism. Risks to federally listed threatened and endangered

species or designated critical habitat, agricultural crops, nontarget native species, and human and animal health are the most important considerations for the PPB regarding releases of new biological control organisms. Although a risk/benefit analysis, which considers the economic benefit of the successful control of the target as part of the decisionmaking for release of an organism, is often recommended (e.g., Greathead, 1995; Stiling and Simberloff, 2000; Bigler and Kölliker-Ott, 2006), APHIS emphasizes environmental safety of the organism primarily because the efficacy of the organism cannot be predicted, and economic benefits of the release may not be realized.

3. Other Plant Pest Permit Applications

In addition to permit applications for the use of biological control organisms, there are a number of other intended uses for plant pests. The methods of permitting for these uses are briefly discussed in chapter 1, section C., Scope and Focus of this EIS. The uses may include the study of physical and behavioral effects of the pest, basic biology, diagnostic evaluations, or even sterile insect technique as a pest control measure. Other uses may involve various educational displays or classroom work.

a. Benefits

Many factors determine whether a given organism needs to be studied in a biocontainment facility. Organisms that need not be contained may be allowed for field release, laboratory and greenhouse studies, educational purposes, the pet trade, or other uses. The benefits from this movement relate primarily to the intended use or research.

Benefits are gained by the interstate movement of plant pests from one part of the country to another regardless of whether the pests are widespread or ubiquitous in the environment. For example, it is advantageous to test crop resistance to key pests in many different parts of the country, but it may be impractical or costly to culture them at that location. Often a company will have a single pest culturing facility, or can buy from a biological supply company that has the expertise and capacity to raise suitable quantities of organisms for the intended purpose. These pests may be seasonal migrants to an area, but remain incapable of overwintering in a given location. Artificially infesting these fields with these pests provides data for a complete season while posing little risk due to this lack of overwintering capability.

Release of large numbers of sterile insects is designed to control or eradicate pest populations at or near the site of release. Considerable effort is made to ensure the number of sterile insects is sufficiently high to reduce the pest population, and the benefits to local growers from pest eradication extend over multiple growing seasons.

APHIS also issues permits for educational purposes. This allows children to handle lower-risk organisms to fulfill requirements in school curricula through a hands-on learning experience in topics such as insect life cycles, diets, and behaviors. The use of permits for the movement of snails may fulfill educational needs or provide contained colonies used for food production.

The interstate movement of earthworms and insects to feed fish, pet reptiles, tarantulas, and amphibians is widespread. These animals provide hours of enjoyment for their owners, but the organisms themselves may pose a risk and are regulated. Earthworms and insects may also be authorized for movement under permit for use as fish bait. In addition, the insects may be kept as pets in their own right.

b. Risks

Permits generally are issued only if plant pests on the permit application are considered widespread, and environmental risks are considered to be minimal. Containment requirements are placed on those species not meeting criteria for movement into the natural environment. Risks can still be mitigated, however, by expanding permit conditions and verifying that mitigations are enforced. For example, potential adverse effects from laboratory and greenhouse work with a given pest or disease can be mitigated by restricting the work to certain times of the year, such as during the winter or when the pest's hosts or host's life stages are not available. This reduces the impact of any unintentional escapes on the environment. Likewise, limiting the size of plots or requiring that pest control measures be taken can reduce the potential for adverse impacts. One example of a pest control measure could be a requirement to plow the field at the conclusion of the experiments. There are concerns about the potential plant pest risks associated with intra-specific variation within some species. The progeny of some insect species collected in a given State or county may be restricted to movement into the environment of only the State or county of origin. Culture of these plant pests out-of-State may be restricted to a biocontainment facility.

Permit conditions for insects provided by biological supply companies for educational purposes often include a letter stating that the insects are not to be released into the environment. The letter may also discuss potential hazards associated with releasing these species. Each request is considered individually, based upon potential pest risk, and the permit conditions are designed to preclude any likely risks associated with the intended use.

4. Soil Permit Applications

Soil can contain numerous animal and plant pests, and/or noxious weed seeds, or other propagules. The diversity of potential pest species in soil includes many high-risk organisms that pose potential environmental

risks. Screening soil for the spectrum of organisms which might be present and harmful is not practical due to the extensive effort and expenses that would be incurred. APHIS' regulations protect the health and value of American agriculture and natural resources from the introduction of destructive plant and animal pests and diseases. Soil from all foreign countries, U.S. territories, and areas within States that are under Federal quarantine can be moved into or through the continental United States only if conditions and safeguards prescribed by the PPB are met.

a. Benefits

Permit applications for soil (PPQ 525A) are made primarily by laboratories that conduct chemical (including DNA/RNA) and geophysical analysis of soil. Occasionally, applications for soil permits identify the use as religious or for landfill disposal. Benefits from soil permitting include the protection of U.S. agriculture and natural resources from the unmitigated movement of soil pests into new locations around the country. Soil permitting allows approved laboratories to engage in a profitable business venture of analyzing soil samples benefiting their clients. For instance, farmers are able to determine the soil nutrient status of their farm to decide on a fertilizer regime. In addition, researchers can obtain analytical results for soil studies, or attorneys may obtain forensic results for a legal case. Allowing unmitigated movement of soil would be costly to agriculture and the environment. Hence, soil permitting provides an essential service to the public while protecting the natural resources of the United States.

b. Risks

Many soil-borne plant pests and devastating animal diseases may be present in untreated soil samples. Accidental spills of contaminated soil could result in the escape and establishment of these pests. If established, their eradication may be expensive or may not be possible. For example, the pale cyst nematode (*Globodera pallida*) is a soil-borne potato pest detected for the first time in the United States in 2006. If left uncontrolled, this quarantine pest presents a serious threat to potato commerce as food and in nursery stock. APHIS is conducting a costly and time-consuming eradication program to eliminate it from the United States. Another example is the soil-transmitted, highly contagious virus that causes foot-and-mouth disease (FMD). FMD does not currently occur in the United States, but the costs associated with a U.S. outbreak would include eradication costs, production losses, and the loss of export markets (Schoenbaum and Disney, 2003).

APHIS prohibits the importation of soil into the United States from foreign sources, and restricts movement within the continental United States, Hawaii, and U.S. territories unless authorized under specific conditions,

safeguards, and controlled circumstances. Required soil safeguards include secure packaging of samples, an inspected handling facility, and adequate sterilization prior to disposal. APHIS finds these safeguards adequate to mitigate the risk associated with soil movement.

B. Permitting Process Alternatives

Environmental consequences of the permitting process alternatives are dependent upon their ability to reduce potential pest risks, and preclude other potential environmental risks. The decision to permit movement or release of an organism can be facilitated or hindered by the amount and quality of information required of an applicant.

In addressing potential impacts from the movement and release of plant pests, there will always be uncertainty of the pest's ability to establish, ability to adapt to other hosts, and ability to spread under natural conditions from the site of release. The potential impacts from this uncertainty make it important for APHIS to regulate most organisms conservatively, based on what is known. It is also important to require sufficient testing to preclude most pest risks and most environmental impacts. The selection among alternatives and permitting components is most strongly influenced by the relative effectiveness at excluding potential pest risks. Independent of the alternative selected, there remain unknown and uncertain characteristics of all organisms proposed for movement and release. Consequently, anticipated outcomes cannot be unequivocally predicted.

For example, when a biological control organism is released into the environment and becomes established, there is a possibility it could move from the target to attack nontarget hosts. Native species that are closely related to the target species are the most likely to be attacked (Louda et al., 2003); however, host shifts by introduced weed biological control organisms to unrelated plants are rare (Pemberton, 2000). If nontarget species were to be attacked, the resulting effects could be environmental impacts that may not be easily reversed. Biological control organisms may spread without human intervention. In principle, therefore, release of the biological control organism at even one site should be considered equivalent to release over the entire area in which potential hosts occur, and in which the climate is suitable for reproduction and survival.

These organisms may not be successful in reducing the target population in the area of release. Approximately 12 percent of all parasitoid introductions worldwide led to significant sustained control of the target pests; however, the majority of introductions failed to provide control of the pest (Greathead and Greathead, 1992) either because introduction did not lead to establishment or establishment did not lead to control (Lane

et al., 1999). Worldwide, reports of biological weed control programs have had an overall success rate of 33 percent (Culliney, 2005). Actual impacts on target populations are known only after release occurs and post-release monitoring is conducted.

Ecological risk assessment is the most critical and difficult part of the overall risk assessment procedure for biological control (Hokannen et al., 2003). The basic steps in the framework for ecological risk assessment include the following—

1. defining ecological context and the selection of appropriate nontarget species;

2. host specificity testing;

3. natural enemy dispersal capability;

4. potential for natural enemy establishment;

5. direct effects on nontarget species;

6. indirect effects on nontarget species; and

7. risk assessment (Hokannen et al., 2003).

Standard protocols for identifying an adverse effect on nontarget species rely on statistics from experimental and monitoring studies. There is usually a tradeoff between the costs of increasing sample sizes (more experimental or monitoring data) and the confidence in the results of this testing. This arises because sampling from populations inherently involves choosing an acceptable error rate that is balanced against the available resources. Sample sizes generally are the limiting factor due to issues such as a shortage of data collected for the nontarget species, limited space/resources for testing or monitoring, and limited funds for research. Further, statistical analyses designed to verify nontarget effects are difficult to substantiate because of the inherent difficulties in identifying "no effect." There truly may be no effect, or it could be that the testing was not statistically sensitive enough to determine whether a no effect occurred (Hoffmeister et al., 2006). Additionally, there is the possibility of rejecting the null hypothesis when true, and accepting the null hypothesis when false (type I and type II errors). When the sample size is small, the likelihood of these types of error increases. For several different reasons then, statistical testing of nontarget species may verify an adverse effect, but is also less likely to verify lack of an adverse effect even if there is none.

General parameters of arthropod life histories can assist the decisionmaker, to some extent, in assessing potential risk. One of these is the breadth of host range. Organisms that feed on many host species (highly polyphagous species) generally pose higher risk than organisms feeding on one or only a few host species (monophagous or stenophagous species) (van Lenteren et al., 2006b). Few natural enemies are strictly monophagous (Zwölfer, 1970).

Another parameter used to assess potential risk is the quality of the parasitic relationship. Although parasites may only inflict some level of harm, parasitoids kill their hosts. Hymenoptera, which can act as facultative hyperparasitoids, are more likely to pose indirect effects than obligate primary parasitoids (Brodeur, 2000). Some parasitoid taxa are more vulnerable to hyperparasitism which could pose an increased risk of apparent competition with native parasitoids (Heimpel et al., 2004). The idiosyncratic nature of the diverse parasitoid life histories requires detailed analyses of individual species and subspecies genetic cohorts to assess the potential risk (Messing et al., 2006).

Host-specificity screening is the most important step required for a potential biological control organism prior to its release into the environment. Regardless of its control potential, only minimal impact on nontarget species can lead to a permit for release. Insects in confinement may exhibit broader host ranges than are normally observed in the field (Blossey, 2003). In interpreting host-range data, there may be confusing effects resulting from test conditions (van Dijken et al., 1986; Sands and van Driesche, 2000). Frequently, test designs may result in either overestimated or underestimated observed host ranges. The overestimates may arise from tests using organisms deprived from their normal hosts for long periods, or in tests using nonhosts in close proximity to the normal host (the observed feeding is due to transference of stimuli).

Underestimates of host ranges may result from tests in which valid, but less preferred, hosts are ignored in the presence of a more preferred host (van Lenteren et al., 2006b). Similar effects are observed for oviposition (egg laying) and other reproductive behavior. Tests in the field can address some, but not all, of these problems associated with laboratory studies.

A comparison of information needed for analysis and the likely environmental outcomes from selection of each alternative is presented in table 4–1. This table expresses how each alternative would be expected to address specific input needed, and potential outcomes in relative terms. The no action alternative (current 7 CFR part 330) forms the baseline for this comparison. Implementation of other alternatives may require comparable effort, more effort, or less effort to meet the analyses of

Table 4–1. Level of Input Needed or Potential Environmental Outcomes for Selection of Each Alternative.

	No Action (Current 7 CFR 330)	Proposed Revision of Part 330 Regulations	Comprehensive Risk Mitigation
I. All Permitting			
A. Native species affected	Best available science—testing may be required	Comparable to No Action	Host range more thoroughly understood before release
B. Ability to adapt to different climatic conditions	Present climatic conditions at time of permitting and known organism traits	Best available science	Increased knowledge of ability to adapt based on more extensive testing
C. Sustained control of target pests	Available control and test data	Comparable to No Action	Understood thoroughly prior to release
D. Pesticide and toxic chemical health	Likely reduced	More likely readily reduced	More likely slowly reduced
E. Allowance for unknowns and	Based upon traits of organism	Comparable to No Action	Least allowances for these issues
F. Unanticipated release via	May occur	Less likely due to standardized packaging	Least likely
G. Containment maintained before movement to the	Likely	More likely due to clearly specified containment requirements	Requirements most likely to ensure containment
II. Entomophagous Biological Control Permitting			
A. Ability to establish	Regulated via policy	Best available science	Greater understanding due to more extensive testing
B. Ability to spread	Regulated via policy	Best available science	Regulated through added requirements
C. Ability to survive beyond one season	Regulated via policy	Best available science	Determined from extensive testing
D. Ability to adapt to other hosts	Regulated via policy	Best available science	Comparable but requires more thorough understanding of adaptation mechanisms
III. Generally Applicable Permitting Requirements*			
A. Ability to establish	Best available science	Comparable to No Action	Greater understanding due to more extensive testing
B. Ability to spread	Best available science	Comparable to No Action	Regulated through added requirements
C. Ability to survive beyond one season	Present climatic conditions and known organism traits	Comparable to No Action	Determined from extensive testing
D. Ability to adapt to other hosts	Results of required testing	Comparable to No Action	Comparable but requires more thorough understanding of adaptation mechanisms

* All permits except entomophagous biological control permitting.

potential impacts. Selection of the other alternatives may pose comparable, greater, or less risk. The timeframes for permit issuance are commensurate with the effort and time required for environmental and pest risk analyses. This table provides the decisionmaker with an idea of what to expect in terms of technical input and environmental outcome from the selection of each alternative. It is clear from the table that selection of each alternative has its environmental benefits and costs.

Although the comprehensive risk mitigation program may be more protective against issues (e.g., nontarget effects), decisions for issuance of permits are slower for organisms that pose no adverse effects, and whose movement offers potential benefits.

The preferred alternative to the regulations requires comparable input to the no action alternative. These revisions would provide more rapid determinations for some organisms (e.g., plant pests) of known risk status; however, the advantages to the regulatory process may not be evident for other organisms whose pest risk status is less clear (e.g., many entomophagous biological control organisms). The greater flexibility in the regulatory permit process makes this alternative preferable to the current approaches under the no action alternative, and to the lower risk tolerance required under a comprehensive risk mitigation program.

1. No Action

The potential environmental consequences of taking no action would not accrue to any substantial degree in the short term; however, the impacts of no changes in the regulations are likely to become increasingly problematic over time. The current regulations in 7 CFR part 330 include certain inefficient processes and practices that pose increased environmental and pest risk. Some of the issues were discussed in the description of this alternative in chapter 2. These are summarized here as they relate to potential environmental impacts. Based upon the current regulations in the CFR, permit applications for organisms already assessed for potential plant risk, and organisms native, already established, or incapable of becoming established are subject to the same review process as required for all other permit applications. This approach is an inefficient use of permitting experience as it places undue focus on plant pests of known risk.

The benefits to the environment from the permitting process, as provided in the preferred alternative, would accrue more readily than under the no action alternative, and beneficial effects could decrease the overall detriments from introduced quarantine pests and noxious weeds. This is particularly true for permitting of some groups of biological control organisms. Paperwork reduction and allowing PPB permit analysts to focus on organisms that pose higher plant pest risks are not facilitated by the current regulations.

As noted in chapter 1, there were considerable increases in the number and intended purposes of permit applications in recent years. The current regulations did not anticipate the number or variety of applications that are currently submitted. Courtesy permits (7 CFR § 330.208) and oral permits (7 CFR § 330.203) could be reviewed by analysts when the number of applications was limited and PPB permit analysts had sufficient time for followup with permit holders. The lack of documentation for these permits limits enforcement, particularly when there are interagency interactions at the ports.

The current regulations do not provide clear direction for review of permit applications by PPB permit analysts. The PPB permit analysts developed criteria based upon pest risk and internal policy, but these criteria are not always transparent to the applicant. This lack of clarity can delay permit issuance, depending upon the applicant's understanding of the information needed to process the permit application. For biological control organisms, delays in impacts as a result of this processing can delay environmental benefits if the movement reduces environmental damage from weeds or pest species. Although these delays may also affect potential adverse impacts and unforeseen effects, this inefficiency does not provide any overall net positive environmental benefits.

Analyses for field releases of organisms (particularly fungi and bacteria of domestic origin) moved interstate require specific review to ensure compliance with APHIS' NEPA Implementing Procedures. Any "Releases into a State's environment of pure cultures of organisms that are either native or are established introductions" must meet certain criteria to apply the categorical exclusion from the need for further documentation (7 CFR § 372.5(c)(3)(iii)(C)). Permit applications not meeting these criteria are subject either to denial of a permit or the need for further environmental documentation under NEPA. This is not expected to change under the proposed rulemaking or under the comprehensive risk mitigation alternative.

The potential impacts from continuation of ongoing practices under the no action alternative can best be assessed by considering the overall benefits and risks that accrued from previous decisions. (These are discussed above in section A of this chapter for classical biological control, plant pest, and soil permit applications.) The relative impact for these requests is compared to that of the other alternatives. Movement of these organisms and soil all pose potential impacts, and the decision to issue a permit is based upon the PPB permit analyst's determination of lack of adverse plant pest risks. The plant pest risk is determined by knowledge of the biology of the pest and the permit conditions. The decision process for all these organisms is less transparent under the current regulations than under the

proposed revision. Rigorous analyses and compliance in the past provided the basis for the proposed revisions.

The alternative for a comprehensive risk mitigation program would involve the most rigorous analysis, but it would not necessarily be the most efficient because of the many uncertainties and unknowns that would create delays to the decision process. The other alternatives make some allowance for these uncertainties and unknowns, but do not focus on the same compliance requirements.

a. Approval of Biocontainment Facilities

Adequate containment is critical to plant protection. Many organisms moved to biocontainment facilities are known to pose substantial environmental and pest risks. The number of inspected biocontainment facilities has increased from fewer than 125 facilities to over 3,100 during the past decade. The dramatic increase in applications for use of organisms within biocontainment facilities, and the associated inspections, created staffing challenges to meet increased demand. Both increased personnel and increased efficiency are critical for verification of compliance at biocontainment facilities. Although some organisms ultimately may be determined to be safe for release into the environment, the damage to plants from an escape due to an inadequately secured facility could be considerable locally or over a wider area if the organism established and disseminated. Regulations governing these facilities are important to precluding pest risks.

The no action alternative involves a status quo approach to inspecting and determining if biocontainment facilities are adequate. The current regulations at 7 CFR § 330.202(b) indicate that the agency is required to "determine whether existing or proposed facilities will be adequate to prevent plant pest dissemination in case a permit is issued." There is no definition or criteria in these regulations for what constitutes "adequate" containment. This lack of guidance and transparency in the current regulations reduces the ability of the applicants to understand the physical features needed for a biocontainment facility.

The proposed rule provides criteria that are the basis for "adequate" containment in a manner that clarifies the intent of these regulations, The no action approach may accommodate the ongoing demand; however, the increasing number of facilities and increased numbers of applications to move organisms into containment facilities are reducing the effectiveness of the current approach. More efficient inspection of facilities ultimately will be needed to effectively preclude environmental and pest risks. The other two alternatives provide extensive approaches to meeting the expected demand.

b. Permits for Biological Control Organisms

Permits for movement of classical biological control organisms are issued contingent on a lack of plant pest risks. As is true for all three alternatives, there is an expectation of reduced expenditures for pesticides, labor, and specialized equipment than would occur with other control measures. The population of the biological control organism is expected to be self-perpetuating and self-spreading within the range of its host, but this characteristic may not be realized in untested environments. Ecological conditions may return to those that preceded introduction of the pest or weed. Although biological control organisms assist in control, their deployment often is only one tool used in integrated pest management. Reductions in expenditures and impacts from the use of pesticides are possible; however, control from these organisms may not completely return the environmental conditions to those prior to pest or weed introduction. The organisms could affect allergenic reactions from exposures resulting from chemical control measures or weeds, but there could be some allergenic responses to the biological control organisms themselves. Although release of the organisms can increase biodiversity, this may or may not result from individual movements of these species. Approval of releases prior to the growing season enables properly designed releases of biological control organisms.

The proposed alternative is anticipated to provide the most timely permit decisions of the three alternatives without posing evident risk. The no action alternative could offer comparable timeliness, but the process would lack transparency and could involve delays for organisms for which pest risks are already analyzed. In addition, the no action alternative would not incorporate the authority provided by the PPA to regulate biological control organisms under the permitting regulations. The comprehensive risk mitigation program would involve more time for review, but would involve more extensive risk mitigation.

Over several decades, a commercial industry has developed to supply biological control organisms for the control of weeds or plant pests. In general, parasites, parasitoids, and predators of plant pests are reared in laboratories in the United States and other countries, and biological control organisms of weeds are harvested from areas where the target weed is growing in the United States and Canada. Currently, permits for commercially supplied biological control organisms are issued for the importation and interstate movement of species that are already established in the environment and/or have been released for many years. The greatest risk proposed by these sources is the possibility of contaminants in the shipment. Examples of contaminants are hyperparasites, misidentified biocontrol species, inclusion of other arthropods, which may include plant pests or enemies of beneficial species, propagative plant parts of weed

species, and plant and arthropod disease organisms (besides those intended to infect a target plant pest or weed).

Under the no action alternative, the primary safeguard consists of permit conditions. APHIS does not attempt to provide or enforce quality controls, or monitor the shipments for the correct identity of organisms, lack of contaminants, or health of the permitted organisms under the no action alternative, except that package inspections may be conducted at APHIS plant inspection stations at ports of entry.

Some changes in policy and practices incorporated into the preferred alternative arose from experience gained by permitting under the no action alternative. To the extent that the preferred alternative better addresses potential effects to nontarget organisms and host specificity, the potential environmental risks are reduced. The inability to establish a population of biological control organisms or to provide measurable control may be more thoroughly assessed under the comprehensive risk mitigation program, but there will always be some uncertainties. Potential risk issues related to contamination, adaptation, interference, competition, and hybridization remain under each alternative. Improved identification and practices that remove parasites and parasitoids are now required, but these were not always critical considerations for prior permitting decisions.

Complete host testing and host shifts remain a challenge under the no action alternative. The comprehensive risk mitigation alternative provides the most complete consideration of these issues, but the ultimate findings still require post-release monitoring. Likewise, competition among predators, parasites, and parasitoids may not be revealed without monitoring. The no action alternative involves the most limited monitoring, mitigation, and compliance efforts of the three alternatives. The risks arising from movement for releases will remain the least understood if this permitting process alternative is selected.

c. Permits for Plant Pests

The movement of plant pests has potential impact issues and uncertainties that are also common to those for movement of biological control organisms. The no action alternative provides the least coverage of these concerns. Addressing issues such as crop resistance, suitable quantities of pest organisms for testing, and control effectiveness of sterile insect technique are all important applicant issues, but their environmental impacts may not be readily evident during review of an application. Permitted research generally is limited to areas where the plant pest is established, release will not add to potential impacts, and site-specific conditions can be monitored. The comprehensive risk mitigation program may require information about the possibility of success to achieve the

intended goal of the applicant, but none of the alternatives address all uncertainty. Independent of the alternative selected, permit decisions to preclude pest risks would be based upon what is known or can be determined about the pest's biology from testing under containment, field cage testing, and field monitoring.

The current regulations did not consider all of the types of permit applications that the agency now receives, so those novel applications are reviewed on a case-by-case basis. The educational benefits from permitting various organisms for use in the classroom are weighed against potential plant pest risks. For butterflies, it is a standard practice to require the applicant to send letters of compliance to end users along with the permit conditions, to ensure that inadvertent releases do not occur. Although this approach is adjusted to cover likely use conditions, based on experience from initial permit applications, there is no evidence that this practice results in substantial increases in pest release. Permits for insects as pet food, and permits for mollusks, involve conditions to preclude movement to the environment. Organisms requested for use as fish bait are required to be treated prior to importation, or are subject to a rigid rearing protocol to reduce plant pest risk. Although plant pest risk is not eliminated in the proposed rule, it is mitigated to a low level. The comprehensive risk mitigation alternative also lowers potential plant pest risks, but it also requires substantially more time and effort by APHIS' staff.

d. Permits for Movement of Soil

Permit applications for movement of soil are submitted to fulfill various purposes by the applicant. Most requests involve some chemical and geophysical analysis, however, some movement relates to use for religious purposes or for research with subsequent sterilization of the soil prior to disposal in landfills. One routine purpose for soil movement involves analysis of the soil nutrient status to determine the need for fertilizer applications, and some analyses relate to forensic investigations. Independent of the intended use of the soil, each application is reviewed on a case-by-case basis and must meet certain safeguarding requirements.

There are conventional ways of treating soil to eliminate potential disease and pest risks. Adherence to these treatments is required of the permit applicant. The review period for a soil permit may be reduced by the inclusion of these routine treatment practices to mitigate risk. These practices are a part of the no action alternative, but are enhanced or specified in the proposed rule. Other than a broader definition of what constitutes soil in the proposed rule, there is no substantial change in the actual treatment practices between these two alternatives. The comprehensive risk mitigation alternative involves more analysis with

associated increases in review time, but not necessarily greater risk reduction.

Most of the noxious weed, animal disease, and plant pest risks associated with the movement of soil involve potential spills or inadequate treatments of the soil prior to disposal. There are a number of agents responsible for adverse animal and human health effects that are associated with soil contaminated by disease organisms, including anthrax, exotic New Castle disease, and FMD. Their presence in the soil can be mitigated by soil treatments, but spills may occur prior to the required treatment. The current regulations do not specify the present policy or practices for packaging and transport. Those requirements are specified in the proposed rule. The conditions for movement generally are designed to ensure that such risks are mitigated. There will always be some uncertainty about associated risks, even with the comprehensive risk mitigation alternative; however, the proposed rule provides adequate mitigation of the most likely environmental risks associated with the movement of soil. Additional requirements under the comprehensive risk mitigation alternative could further reduce potential risks; however, the net increase in protection may not be justified based upon the additional costs of safeguarding.

2. Proposed Revision of Part 330 Regulations (Preferred Alternative)

The potential environmental consequences of the proposed revision arise from the decreased risks from movement, as compared to the current regulations. The revisions to the permit review process, as proposed here, improve efficiency of the permitting process. For example, the proposed exceptions from permitting for certain biological control organisms that are established throughout their geographical range results in a streamlined decision process for removing routine permit applications for these organisms and providing transparent guidelines detailing the information needed to add a biological control organism to the exemption list.

Similarly, the development of exceptions to permitting requirements for interstate movement of certain plant pests also provides a mechanism for removing routine permit applications for certain organisms. This allows for more effective use of staff time and less dependency on paper documentation than past practices. This also allows PPB permit analysts to spend more time on those applications that have higher potential risks and greater need for designing specific permit conditions to mitigate those risks. Each of these benefits the human environment because they assist the permit applicant, the PPB permit analyst, and the decisionmaker. These revisions are critical for keeping pace with the increasing numbers and variety of permit applications.

The proposed regulations place restraints on the method of proposed movement of the organisms, packaging, and labeling. In the past, these

requirements were open to considerable interpretation which led to increased potential for unintentional release. The specific conditions decrease the likelihood of environmental and pest risks for different organisms, and different means of transport. In particular, the special conditions for transport by hand-carry and use of packaging consistent with potential risk provide better protection than in the past. These conditions are also consistent with the requirements of the U.S. Department of Transportation which decrease the likelihood of carrier error resulting in pest escape. Organisms listed as excepted from permitting requirements (under PPA section 411; 7 U.S.C. 7711) would not be required to meet any packaging, labeling, hold or inspection requirements because excepted organisms must move, "without further restriction."

Under the proposed revision, the elimination of oral and courtesy permits ensures potential environmental and pest risks associated with all applications will be given adequate consideration and documentation. The PPB has not issued these permits in recent years. Elimination of these permits provides greater consistency and improves interagency regulatory interactions.

a. Approval of Biocontainment Facilities

As previously discussed, the current regulations at 7 CFR § 330.202(b) require APHIS to "determine whether existing or proposed facilities will be adequate to prevent plant pest dissemination in case a permit is issued," but the regulations do not provide a definition or criteria for what constitutes "adequate" containment. The proposed revision will not codify the requirements for biocontainment facilities to prevent the dissemination of plant pests, but would provide web-based guidelines to permit applicants and permittees. Biocontainment guidelines provide transparent yet flexible options for plant pest containment to potential permittees.

Unlike the current regulations, the proposed revision provides detailed conditions for packaging, labeling, and means of transport. These would involve additional monitoring and verification of compliance with permit conditions, however the level of effort would be considerably less than for the comprehensive risk mitigation alternative. This alternative may require notification of destruction of the permitted organisms to the PPB, but lacks verification of their proper disposal when they are no longer reared at the facility.

Inspection procedures would continue to develop with practice and experience over time. Inspections would not be required of all overseas facilities that send organisms to the United States for direct environmental release, as would be included in the comprehensive risk mitigation

alternative. Likewise, any verification of the identity of organisms and the purity of cultures would be limited to post-arrival sampling. This would reduce contamination and inaccurate descriptions of the organisms, but is not expected to provide the same level of pest risk reduction as the comprehensive alternative. Tracking of shipments in the APHIS electronic permitting system could be expanded to some degree, however, it would not be as extensive as required at the ports of entry under the comprehensive risk mitigation alternative.

b. Permits for Biological Control Organisms

The PPA specifically provides APHIS with regulatory authority for biological control organisms; the proposed regulations will incorporate this authority, thus providing stronger oversight. This change in authority allows APHIS to regulate the importation, interstate movement, and intrastate movement terminating in environmental release of both weed and entomophagous biological control organisms. Under this alternative, the revised 7 CFR part 330 regulations would incorporate the authority of the PPA to regulate the movement of both weed and entomophagous biological control organisms by permitting. The revised regulations would also allow for exceptions to these permitting requirements for certain biological control organisms that have become established throughout their geographical range in the continental United States, such that the additional release of pure cultures of these organisms into the environment of the continental United States will present no additional plant pest risk to plants or plant products.

This approach provides a more transparent basis for determining potential restrictions on movement than do the current regulations. This approach facilitates more rapid decisionmaking for the movement of organisms. The benefit for biological control organisms that pose no plant pest risks to agriculture is that their more timely release has the potential to provide earlier control of the target pest or weed.

There are a number of indirect benefits that can result from release of biological control organisms into the environment, but these are not always recognized or readily detected. Generally, there is a reduced need for use of chemical control measures when biological control organisms are effective. This reduced use of pesticides, and other chemical control measures, decreases the likelihood of human exposure to these substances which, thereby, also reduces potential adverse health effects, including hypersensitivity reactions or multiple chemical sensitivity reactions. Likewise, the biological control of weeds can reduce production of pollen for some plant species and, thus, reduce the potential risk of allergenic reactions from individuals sensitive to the pollen. However, it is also possible that some individuals could have allergenic responses to the

biological control organisms themselves. Increased damage to the target plants of concern would be expected for successful establishment of the biological control organisms, but feeding on nontarget species and unexpected host shifts remain an impact of concern. Increased review before first-time releases of entomophagous biological control organisms would increase the time it would take before new organisms are released into the environment, compared to the no action alternative, but would also increase the level of protection of agriculture and the environment.

Permit application review, under the preferred alternative, simplifies and makes the permitting process more consistent in a manner that increases efficiency; however, the lower risk tolerance applied in the comprehensive risk mitigation alternative is more rigorous. The changes in policy and practices that are incorporated into the preferred alternative are the result of many years of experience from permitting under the no action alternative. Potential risk issues related to contamination, adaptation, interference, competition, and hybridization are addressed more thoroughly under this alternative, but uncertainty remains as to how an organism will respond in natural field conditions. Defining adequate host testing and assessing potential host shifts remain challenging under this alternative, particularly for entomophagous biological control. Although the comprehensive risk mitigation alternative would provide the most consideration for these issues, unforeseen potential impacts to host and nontarget species can only be verified by post-release monitoring. In the absence of extensive testing, impacts from competition among predators, parasites, and parasitoids may not be evident prior to monitoring. For these reasons, required identification and methods for filtering out predators, parasites, and parasitoids are practices included in the proposed regulations. The most extensive testing, monitoring, mitigation, and compliance efforts would occur under the comprehensive permit risk reduction alternative; however, uncertainties over the risk from movement for releases would remain.

c. Permits for Plant Pests

The proposed regulations would allow for exceptions to the permitting requirements for certain plant pests that are (a) established throughout their geographical range within the continental United States, or (b) are commercially produced under Government oversight. This approach provides a transparent basis for APHIS' determinations of no pest risk. It also facilitates more rapid decisionmaking for the movement of plant pests because a one-time decision takes the place of evaluating individual permit applications. Agency convenience is also enhanced by undefined time limitations for the consideration of a listing or reconsideration after public comment. The benefits to users of organisms that meet one of the criteria

and become listed is their more timely movement and use of these organisms.

For plant pests not listed as exceptions, potential impact issues and uncertainties for their movement are similar to those already discussed for movement of biological control organisms. The preferred alternative offers more efficient coverage of plant pest concerns than does the no action alternative. Addressing issues like crop resistance, suitable quantities of pest organisms for testing, and control effectiveness of the sterile insect technique are all important applicant issues; however, quantifying potential environmental impacts related to these topics would most likely require thorough review under the comprehensive risk mitigation alternative. Permits for release of plant pests generally are limited to areas where the plant pest is established; nevertheless, movement from the area of release is expected to occur. Permit conditions under each of the alternatives are designed to preclude unacceptable plant pest risks.

The educational benefits from permitting various organisms in the classroom are an important consideration when weighing potential plant pest risks from movement of an organism. For butterflies, letters of compliance from the applicant to move the organisms, along with permit conditions, are sent with the organisms to mitigate the likelihood of unintentional release by educational users. This is designed to ensure the permit conditions are conveyed to the end users. There is no evidence that this practice has resulted in substantial increases in pest release; therefore, permit conditions and pest mitigation beyond those being proposed do not appear to be justified at this time.

Requirements and other permit conditions for movement of mollusks for educational use and insects used as pet food have been shown to effectively preclude movement into the environment. As with the no action alternative, the preferred alternative requires organisms intended for use as fish bait be treated prior to importation, or are subject to a rigid rearing protocol to reduce the potential plant pest risk. The proposed regulations cover most pest risks for the anticipated uses for which organisms are expected to be moved, but some novel applications will need to be reviewed on a case-by-case basis. This alternative contemplates a broader range of permit requests than the current regulations and, therefore, provides enhanced consideration of mitigations. The proposed rule is designed to mitigate plant pest risk to a low level, but there will always be uncertainty associated with compliance. The comprehensive risk mitigation alternative involves increased compliance efforts and greater review based upon more substantial information requirements; however, this would not necessarily provide more complete pest risk reduction than the preferred alternative.

d. Permits for Movement of Soil

The proposed rule has a broader definition of what constitutes soil; however, there is only one substantive change to the actual permitting process relative to the no action alternative. In general, every permit application for movement of soil would continue to be reviewed on a case-by-case basis and must meet safeguarding requirements, unless an exemption is met.

Unlike the current regulations, the preferred alternative specifies the policy and practices for packaging and method of proposed movement of soil. The conditions for movement of soil are designed to ensure the most likely environmental risks are mitigated.

3. Comprehensive Risk Mitigation Program

The environmental consequences of promulgation of a comprehensive risk mitigation program for permitting the movement of plant pests and soil are expected to be less than under the other two alternatives based on more extensive testing and more comprehensive risk reduction requirements. However, this effort requires human, fiscal, and infrastructure resources that exceed those currently available, or are likely to be made available, to the PPB. Although not all provisions of this alternative can be initiated in an effective and efficient manner at present, their implementation may become logistically feasible as the Agency continues to accrue data about permit regulation streamlines other PPB review functions.

The broad risk mitigation strategy for this comprehensive risk alternative includes provisions to preclude environmental and pest risks by not restricting permit conditions to address only known risks. This alternative maintains strict conditions for packaging, labeling, means of transport, and containment. This alternative includes applying and monitoring proven and potential mitigations. There would be plans for enforcement, monitoring, and remediation of any unforeseen impacts. This greater level of oversight reduces potential risks and impacts, but requires more substantial permitting infrastructure than is currently available.

The use of extensive administrative categories under this alternative divides organisms for regulation by level of plant pest risk, level of containment required, type of movement, purpose of movement, and type of establishment. These features would assist in determining the placement of organisms for setting appropriate permit conditions and providing potential risk mitigations. These categories would be applied to both biological control organisms and plant pest species. This alternative would provide more extensive environmental protection, mitigations, and greater oversight than would the other two alternatives.

a. Approval of Containment

The comprehensive risk mitigation alternative would apply strict criteria to ensure "adequate" containment. There would be more extensive requirements for monitoring and compliance with permit conditions than the other two alternatives. At the expiration of the permit, this alternative would require verification of proper disposal of the permitted organisms no longer reared at each facility. This would ensure that contained organisms were secured at the end of their use, thereby eliminating potential pest risk.

Unlike the other two alternatives, inspection would be required of all overseas facilities that send organisms to the United States for direct environmental release, such as commercial shipments, biological control organisms, and earthworms for fish bait. Part of the review process would include verification of the identity of all organisms and the purity of cultures imported into the United States before transport. This would preclude country of origin contamination of shipments or inaccurate description of the organisms to be shipped. The preshipment verification of facility compliance and organism quality mitigates against undesirable introductions. There would be further verification of biosecurity by the tracking of shipments coupled with checks at ports of entry. Each of these actions serves to monitor secure movement and precludes unintentional or premature release of organisms.

b. Permits for Biological Control Organisms

Under this alternative, the issuing of permits to move an entomophagous or weed biological control organisms into the environment would be explicitly required to be based upon clear evidence of the potential benefit and unequivocal mitigation of potential risks. Host-specificity testing prior to the initial movement of organisms into the environment would be required, based upon the known potential pest risk and known organism-plant interactions. In the other alternatives, the applicant is expected to conduct host-specificity testing or provide data about host preferences. In contrast, this alternative involves expanded PPB permit analyst review and specification of the hosts for which data will be required. This alternative envisions the PPB permit analyst's additional review of museum records, field observations in the area of origin, physiological observations, behavioral observations, ecological observations, and experimental results prior to issuance of any permits. Potential risk issues related to contamination, adaptation, interference, competition, and hybridization would be required to be addressed most thoroughly under this alternative. Nevertheless, uncertainty remains as to how an organism will respond in natural field conditions. Data addressing these issues would be submitted to the PPB for review under all three alternatives, however the level of

documentation required of the applicant would be substantially expanded under this alternative.

Under the comprehensive risk mitigation alternative, commercial providers of biological control organisms would be subject to additional inspections and monitoring to ensure shipments do not contain contaminants or misidentified organisms. Although this approach would be expected to provide the greatest protection against the inclusion of contaminants in shipments, it would require commitments for visitations, quality control sampling, identifications, and documentation in excess of what can be handled by current funding and staffing levels.

In addition to information supplied by the applicant prior to permit issuance, this alternative would require the permit holder to provide additional data after movement of organisms into the environment. For biological control organisms, this would include information about the outcome of the release, including the establishment, efficacy, any nontarget impacts, and characteristics of the released organism in the environment. The extensive reporting requirements for this monitoring would be specified in the conditions for each permit. This information would refine pre-movement documentation, and influence the issuance of future permits while ensuring that required data covers all potential impacts prior to issuance of a permit.

c. Permits for Plant Pests

Under the comprehensive risk mitigation alternative, many of the requirements for biological control organisms (as described above) also would apply to plant pests. This includes information about benefits and risks, host-specificity testing, records reviews, and post-movement outcome review. For plant pests released into the environment, this could include information about pest establishment and observations on the range and dispersal from the release site. Each of these requirements serves to provide further protection against potential plant pest risks.

Unlike the other alternatives, the comprehensive risk mitigation alternative would require consideration of issues such as crop resistance, suitable quantities of pest organisms for testing, and control effectiveness of the sterile insect technique. Permits for release of potential plant pests generally are limited to areas where the plant pest is established; however, this alternative would involve looking at effects on the local pest and host populations, as well as the extended effects on surrounding areas of inundative releases.

Under the other alternatives, submission of letters of compliance and permit conditions to end users for educational purposes is limited to the

movement of butterflies. This has served to advise those receiving shipments of the risks associated with release of the butterflies, and the importance of adhering to permit conditions to prevent inadvertent release. Under the comprehensive risk mitigation alternative, these letters of compliance and permit conditions would be required for movement of all organisms for educational uses. There would be additional requirements for verification of proper handling and disposal by the recipient of the organisms under the comprehensive risk mitigation alternative. Imposition of additional permit conditions and pest mitigations beyond those of the proposed alternative may not adequately reflect the generally low plant pest risks associated with educational uses.

Pet food and fish bait pose low environmental and pest risks for the permitted species. More thorough case-by-case review for the broad range of permit requests would likely be under the comprehensive risk mitigation alternative. It would be anticipated that this alternative would apply restrictions to certain species and biotypes, as well as potential destinations. Quality control monitoring would be required of the permit holders. The comprehensive risk mitigation alternative takes a lower risk tolerance approach to preclude plant pest risks, but there will always be uncertainty about compliance with permit conditions. More substantial review under this alternative would provide the most complete information to inform permit decisions about environmental and pest risk reduction of the three alternatives.

d. Permits for Movement of Soil

Each permit request for movement of soil is reviewed on a case-by-case basis, and must meet certain safeguarding requirements. The review period for a soil permit may be decreased by the intent of the applicant to use some routine treatment practices. Under the comprehensive risk mitigation alternative, permit review could involve more analysis than the other alternatives with associated increases in time to issuance of permit, but not necessarily greater risk reduction.

The comprehensive risk mitigation alternative would involve extensive efforts to verify compliance with specific policy requirements and practices for packaging and transport. The conditions for movement would be designed to mitigate all potential environmental risks associated with the movement of soil. The compliance activities would include close interactions with CBP and common carriers (e.g., the U.S. Postal Service, Federal Express, and United Parcel Service) to ensure that handling and movement of packages precludes the inadvertent release of pests or disease organisms. Under the comprehensive risk mitigation alternative, the additional requirements would further reduce potential risks; however, the increased costs of safeguarding also would be substantial.

C. Special Permit Process Considerations

1. Applicable Environmental Statutes

In the planning and implementation of its programs and actions, APHIS complies with a variety of environmental statutes and regulations. Most of those statutes and regulations require Federal managers to comprehensively consider the environmental consequences of their actions before making any firm decisions. In addition, the statutes and regulations provide guidance about the procedures that must be followed, about the analytical processes involved, and about how to best obtain public involvement. This EIS is prepared specifically to meet the requirements of NEPA (42 U.S.C. 4321 et seq.).

APHIS complies with environmental regulations and statutes as an integral part of the decisionmaking process, to identify and consider available alternatives which lead to more successful outcomes and programs. NEPA is the origin of current APHIS environmental policy. It requires each Federal agency to publish regulations implementing its procedural requirements. APHIS originally published the "APHIS Guidelines Concerning Implementation of NEPA Procedures" (44 CFR 50381–50384, August 28, 1979). Subsequently, the APHIS NEPA Implementing Procedures (7 CFR part 372) superseded the earlier guidelines, and were most recently revised on March 10, 1995. APHIS bases its environmental compliance on NEPA; CEQ's "Regulations for implementing the Procedural Provisions on the National Environmental Policy Act," 40 CFR part 1500, et seq.; the U.S. Department of Agriculture's "NEPA Regulations," 7 CFR 1b, 3100; and the APHIS "National Environmental Policy Act Implementing Procedures."

a. The National Environmental Policy Act

NEPA requires Federal agencies to consider potential environmental consequences in planning and decisionmaking processes. It requires the agencies to prepare detailed statements (EIS') for major Federal actions which significantly affect the quality of the human environment. These documents must consider:

- the environmental impacts of the proposed action (i.e., adverse effects which cannot be avoided should the proposal be implemented),
- alternatives to the proposed action,
- the relationship between local and short-term uses of the human environment,
- the maintenance and enhancement of long-term productivity, and

- any irreversible and irretrievable commitments of resources necessary to implement the action.

NEPA provides the basis for many other statutes and environmental regulations within the United States.

NEPA established the President's CEQ, which published regulations for the implementation of NEPA that became effective in 1979 (40 CFR parts 1500–1508). Those regulations were designed to standardize the process that Federal agencies must use to analyze their proposed actions. Those regulations have been the models for the NEPA implementing regulations promulgated by Federal agencies.

b. The Endangered Species Act

The Endangered Species Act (ESA) (16 U.S.C. 4332 et seq.), provides a Federal mechanism to protect threatened and endangered species. Compliance with this act involves an analysis of the impact of Federal programs and actions upon listed species. Under ESA, animal and plant species must be specifically listed to gain protection. Federal agencies that propose programs and actions which could have an effect on threatened and endangered species that are listed or proposed to be listed, or on designated or proposed critical habitat, must prepare biological assessments for those species potentially affected by their programs and actions. Those biological assessments analyze potential effects, and describe any protective measures the agencies will employ to protect the species or habitat. A consultation process in compliance with section 7 of the ESA is employed, as needed. Consultation under ESA occurs with the U.S. Department of the Interior's FWS and/or U.S. Department of Commerce's National Marine Fisheries Service (NMFS). Such consultation is important to APHIS' environmental process as it then becomes an integral part of the proposed program. Details of compliance with ESA, in regard to APHIS' regulations under the permit process for plant pests, are provided in this chapter in section C.3, Special Concerns.

c. Executive Order 12114—Environmental Effects Abroad of Major Actions

Executive Order (EO) 12114, "Environmental Effects Abroad of Major Actions," was written to require Federal officials to become informed of pertinent environmental considerations, and to take them into account along with other national policy considerations, when making decisions regarding certain kinds of Federal actions, generally those that would have significant effects outside the jurisdiction of the United States. The EO specifically covers major Federal actions that significantly affect—

(1) the global commons (environment outside the jurisdiction of any nation);

(2) the environment of nations not participating in or involved in that action;

(3) the environment of a foreign nation by providing to that nation a product that is toxic or radioactive and prohibited or regulated in the United States; and

(4) natural or ecological resources of global importance designated by the President.

EO 12114 (section 2–4) specifies the kinds of documents to be used for each class of actions listed above. The types of documents include EIS' (generic, program, or specific), bilateral or multilateral environmental studies, and concise reviews (including EAs, summary environmental analyses, or other appropriate documents). For some actions, EO 12114 stipulates NEPA-type documents be prepared; however, NEPA procedures do not apply. Although EO 12114 states that nothing contained in it invalidates any existing regulations of an agency under NEPA and other environmental laws, it explicitly states that it "represents the United States government's exclusive and complete determination of the procedural and other actions to be taken by Federal agencies to further the purpose of NEPA, with respect to the environment outside the United States, its territories and possessions" (section 1–1). Because of its specificity regarding the type of document to be prepared (based upon class of action), EO 12114 should be considered as the exclusive procedural guidance for that determination.

Compliance with EO 12114, in regard to APHIS' permit processes for the movement and release of plant pests, is discussed below in section 3 under Special Concerns.

d. Executive Order 13175—Consultation and Coordination with Indian Tribal Governments

EO 13175 "Consultation and Coordination with Indian Tribal Governments" requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including actions that have substantial direct effects on one or more Indian Tribes. When the geographical area potentially affected by the movement of biological control organisms, weeds, and plant pests could include Tribal lands, APHIS contacts the appropriate Tribal authorities to request consultation with them.

e. Executive Order 12898—Environmental Justice

EO 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," focuses Federal attention on the environmental and human health conditions of minority and low-income communities, and promotes community access to public information and public participation in matters relating to human health or the environment. This EO requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participating in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.

f. Executive Order 13045—Protection of Children from Environmental Health Risks and Safety Risks

EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks," acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and appropriate, and consistent with the Agency's mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children. It also establishes a task force, requires the coordination of research and integration of collected data, gives guidelines for the analysis of effects, and directs the establishment of an "Interagency Forum on Child and Family Statistics."

Both EO 12898 and EO 13045 call for special environmental reviews in certain circumstances. In particular, when first time environmental releases of biological control agents or other organisms are proposed, special environmental reviews may be necessary. APHIS can use EJSCREEN (available at https://toolkit.climate.gov/tool/ejscreen-environmental-justice-screening-and-mapping-tool), EPA's environmental screening and mapping tool that provides demographic and environmental information for a geographic area. APHIS can reach out to minority and low-income populations when necessary by using radio, television, newspapers, the APHIS stakeholder registry, and social media, as well as other techniques outlined in "Promising Practices for EJ Methodologies in NEPA Reviews" (FIWGEJ and NEPA Committee, 2016).

g. Executive Order 13112—Invasive Species

EO 13112, "Invasive Species," directs Federal agencies to use their programs and authorities to prevent the spread or to control populations of alien species that cause economic or environmental harm, or harm to human health. Alien species are, with respect to a particular ecosystem, any species including its seeds, eggs, spores, or other biological material capable of propagating that species that is not native to that ecosystem.

Many of the plant pests considered in permit applications are classified as invasive, alien species. In this EIS, identification of some of those species and the proposed alternatives for regulation and containment of the invasive species serves to fulfill obligations under NEPA and under this EO.

h. Miscellaneous Federal and State Environmental Statutes

APHIS complies with a number of other environmental acts, statutes, and regulations. Examples of these include the—

- Migratory Bird Treaty Act;
- Bald and Golden Eagle Protection Act;
- Federal Insecticide, Fungicide, and Rodenticide Act;
- Substances Control Act;
- Resource Conservation and Recovery Act;
- Comprehensive Environmental Response, Compensation, and Liability Act of 1980;
- Clean Air Act; Clean Water Act; and
- Food Quality Protection Act.

Environmental compliance with these statutes must be verified before any program, rulemaking, or permitting action is undertaken.

The potential States where releases and containment facilities occur have various environmental statutes and regulations. Many of the regulations and regulatory organizations that enforce these are direct parallels of the Federal regulations and regulatory organizations. California, for example has the California Environmental Quality Act, and has formed the California Environmental Protection Agency.

For parallel programs and initiatives, APHIS will work with State and/or other Federal agencies to implement permit-specific actions. APHIS will rely on its State cooperators to identify applicable State environmental regulations to take the lead for their procedures, and to ensure full compliance with State laws.

2. Applicable International Conventions and Guidelines

There are a number of international agreements involving the movement of plant pests for which the United States is a signatory.

a. 1992 Convention on Biological Diversity

The 1992 Convention on Biological Diversity directs signatory countries to require various practices to protect their biological diversity. In particular, article 8(h) states that each contracting party commit themselves to "prevent the introduction of, control, or eradicate those alien species which threaten ecosystems, habitats or species." Signatory countries have committed themselves to incorporating this agreement into their laws. The United States became a signatory to this international treaty on June 4, 1993. Under this treaty, it is expected that a thorough evaluation will be completed before importing or introducing alien species or strains into a country.

b. International Standards for Phytosanitary Measures (ISPM) No. 3

The International Plant Protection Convention (IPPC) is an organization designed to promote international cooperation for controlling and preventing the spread of harmful plant pests. The most recent revision to IPPC was adopted by the United States in 2001. The standards, guidelines, and recommendations developed by IPPC have been specifically recognized by the World Trade Organization since 1995. The Guidelines for the Export, Shipment, Import, and Release of Biological Control Agents and other Beneficial Organisms (ISPM No. 3) have been recognized as the international standard since 2005. Although these IPPC-approved documents are only guidelines; IPPC members consider them to be "standards." When approved, there is a general obligation for member countries to abide by the conditions of the standard. APHIS' regulations governing the movement of biological control organisms are designed for consistency with the terms of ISPM No. 3.

3. Special Concerns

There are a number of issues that directly relate to the applicable environmental statutes described above, or to potential impacts generally associated with agency actions. These special concerns are discussed in this section.

a. Endangered Species Act Compliance

(1) Policy

USDA Departmental Regulation, Fish and Wildlife Policy No. 9500–4, dated August 22, 1983, and updated April 28, 2008, sets forth the purpose, policy, and responsibilities of USDA with respect to fish and wildlife.

Agencies of USDA will not fund or take any action that is likely to jeopardize the continued existence of threatened or endangered species, or destroy any habitat necessary for their conservation. USDA will coordinate with the Secretaries of the Department of the Interior and the Department of Commerce in the administration of ESA and animal and plant quarantine laws.

Section 7 of the ESA and ESA's implementing regulations require Federal agencies to ensure that their actions are not likely to jeopardize the continued existence of federally listed threatened and endangered species, or result in the destruction or adverse modification of critical habitat. APHIS considers potential impacts on federally listed species and critical habitat, and consults with FWS and/or NMFS when impacts to listed species are a possibility from the first-time release of a nonindigenous organism, including arthropods and pathogens for control of weeds and plant pest arthropods, and other domestic new area inundative releases on a case-by-case basis.

(2) Benefits and Unintended Consequences to Threatened and Endangered Species and Critical Habitat

Invasive plant and insect species can have adverse impacts on listed species and their habitats. Invasive species are either a primary or secondary threat for 58 percent of federally listed insects in the United States (Wagner and Van Driesche, 2010). The introduction of natural enemies from the native range of the invasive species (classical biological control) can provide a method of host-specific, targeted control of invasive species with fewer nontarget effects than other methods, such as chemical or mechanical removal. Biological control may be used as a method for recovery of listed species. For instance, habitat loss and invasion of riparian habitat by introduced exotic plant species (e.g., the invasive plant *Arundo donax* (*A. donax*)) is a primary reason for the listing of the endangered least Bell's vireo (*Vireo bellii pusillus*) (FWS, 2006). The draft recovery plan for least Bell's vireo indicates that developing biological control methods for *A. donax* is a high priority recovery action for the species (FWS, 1998). Biological control can be highly cost-effective, environmentally sustainable, and can avoid the use of pesticides (Cruttwell McFayden, 1998; Charudattan, 2001; Hoddle, 2004).

There are few examples of weed biological control organisms with potentially adverse effects on federally listed species. The most well-known example is that of the flowerhead weevil (*Rhinocyllus conicus*) which was introduced into the United States in 1969 to control Eurasian thistles (*Carduus* spp.). However, the flowerhead weevil was found to utilize native *Cirsium* thistles (Turner et al., 1987), and there is concern that it may pose a serious threat to the Pitcher's thistle (*Cirsium pitcheri*), a federally listed threatened species (Louda et al., 1997; Louda et al., 2003a; Louda et al., 2005). There are a few examples of potential adverse effects to listed species due to unintentional releases of weed biological control organisms in the United States. The South American cactus moth (*Cactoblastis cactorum* (*C. cactorum*)) was introduced to the Caribbean for control of invasive prickly pear cacti (*Opuntia* spp.). It was unintentionally introduced into Florida in 1989; now *C. cactorum* attacks five native Florida *Opuntia* species, including the extremely rare semaphore cactus (*Opuntia spinosissima*) (Stiling et al., 2000; Stiling, 2002). The federally listed Bakersfield cactus (*Opuntia treleasii*) is a likely target of the moth should it reach California. Another weed biological control organism, *Mogulones cruciger* (*M. cruciger)*, a weevil introduced into Canada for the control of houndstongue (*Cynoglossum officinale*), has been confirmed in Washington and Montana as a result of releases in Canada. Available data suggest that *M. cruciger* may pose risks to native Boraginaceae, including rare and endangered species in the United States (Andreas et al., 2008).

Specific examples of entomophagous biological control organisms adversely affecting threatened or endangered arthropods have not been documented in literature. Hopper (1995) analyzed potential impacts on threatened and endangered insect species from introductions of parasitic wasps released for control of various agricultural pests and found low impact. Although information on nontarget impacts, as a result of biological control, is sparse, others have concluded that attack on rare native species by biological control organisms can accelerate their decline (Howarth, 1983; Howarth, 1991; Louda et al., 2003b).

(3) Analysis of Potential Impacts on Threatened and Endangered Species and Critical Habitat

The PPB considers both direct and indirect impacts to listed species and critical habitat when considering issuance of permits for environmental release of candidate exotic biological control organisms. Direct impacts include feeding, oviposition, and development of weed biological control on listed plants, and direct parasitism of listed arthropods. Indirect impacts on listed species that are considered include listed species usage of the target weed for nesting, cover, or as a food or nectar source, especially if the target weed is considered an essential physical or biological feature of

designated critical habitat, or if the target arthropod is an important food source or pollinator to a listed species.

Researchers submitting petitions to the PPB for review by the Technical Advisory Group for Biological Control Agents of Weeds (TAG) are required to submit information on threatened and endangered species, including plant species in the same family and genus as the target weed, species likely to be found in the same habitat and range as the target weed, justification for listed species or surrogates used in host-specificity testing, and host-specificity test data. Researchers submitting petitions for release of entomophagous biological control organisms also include information regarding possible direct or indirect effects on threatened and endangered species in North America and host-specificity data. The PPB evaluates the information submitted in these petitions, as well as other available scientific publications, and prepares a biological assessment to determine if the candidate organism may affect federally listed threatened and endangered species or designated critical habitat. If the PPB determines that an organism is likely to adversely affect a federally listed species, the proposal is generally not considered further and the permit application to release the organism into the environment is denied. If a "may affect, not likely to adversely affect" determination can be made, the PPB submits the biological evaluation to FWS requesting concurrence with its determination. No effect determinations are documented in EAs that are prepared for the environmental release of any proposed nonindigenous organism for biological control.

b. Analysis in Compliance with Executive Order 12114

EO 12114, "Environmental Effects Abroad of Major Federal Actions," requires Federal officials to become informed of pertinent environmental considerations and take them into account, along with other national policy considerations, when making decisions on Federal actions that would have significant effects outside the jurisdiction of the United States. This EO specifically covers major Federal actions that significantly affect (1) the global commons (environment outside the jurisdiction of any nation), (2) the environment of nations not participating in or involved in the action, (3) the environment of a foreign nation by providing to that nation a product that is toxic or radioactive, and prohibited or regulated in the United States, and (4) natural or ecological resources of global importance designated by the President.

EO 12114 (section 2–4) specifies the kinds of documents to be used for each of these classes of action. To the extent that the actions considered in this EIS include cooperative work in foreign nations and potential effects to the global commons, this EIS addresses those environmental effects abroad. It is recognized that importation of plant pests and associated

commodities involve enforcement of regulations at the ports of entry. These regulations are designed to reduce delays at these ports, to the extent possible, while still providing the requisite mitigation of pest risks. The potential environmental consequences for rearing facilities and biological control release programs in these nations are expected to be comparable to those for such actions in the United States. The requirements for these facilities are designed to reduce the potential movement of plant pests, and thereby reduce environmental and pest risks. This EIS addresses the broad process issues related to these topics, and cites permit-specific concerns abroad, where applicable.

c. Hypersensitivity

Hypersensitive humans experience toxicological symptoms and signs at exposure levels much lower than those that are required to produce the same symptoms in the majority of the population. Hypersensitive individuals constitute only a small portion of the total population. Some individuals are highly sensitive to exposure to insect parts from moths or flies. In particular, the scales from moths are known to induce allergic reactions. Some individuals are highly sensitive to fungal spores or saprophytic (derives its nourishment from dead or decaying organic matter) molds that may induce asthmatic symptoms or allergic responses that may be in permitted shipments as contaminants.

If the response of the population being studied follows the varying doses in a normal distribution (bell-shaped curve), the hypersensitive individuals would be expected to be on the left side of the curve. The increased genetic susceptibility of these individuals is quite variable. Although a margin of safety factor of 10 (uncertainty factor) has traditionally been used by regulatory agencies (National Academy of Sciences, 1977) to account for intraspecies variation or interindividual variability, human susceptibility to toxic substances has been shown to vary by as much as three orders of magnitude (Calabrese, 1984).

Individual sensitivity to effects from exposures is known to be strongly influenced by several factors including age, nutritional status, and disease status. Individuals with immune systems that are less developed or that are compromised physically are likely to be more hypersensitive. The hypersensitive individuals, therefore, would be expected to include larger proportions of the populations of the elderly and young children than other subgroups of the population.

There is no single established mechanism or measurable biological marker associated with the reported reactions of individuals who purportedly suffer from multiple sensitivities. Thus, there is no established physiological relationship to individual exposures. The etiology of

multiple chemical sensitivity is, therefore, very subjective. The reactivity of this group of individuals cannot be effectively evaluated because there are no objective criteria to use to evaluate specific agents or organisms. Based upon the current state of knowledge, individual sensitivity to released plant pests and biological control organisms cannot be specifically predicted. To the extent that movement leads to the establishment of the biological control organisms, there may be reduced need to apply pesticides with an associated potential for reduction in human hypersensitivity reactions. Establishment of plant pests, on the other hand, may result in an increased need for pesticides and an increase in hypersensitivity reactions.

d. Psychological Effects

Program actions, including biological control and plant pest releases, may elicit psychological effects in some members of the general population. Although the permitted organisms are unlikely to affect the health of persons, the lack of familiarity with the introduction of a new organism into local areas can give some persons anxiety. Misinformation or misperception could lead to unfounded distrust of programs when actions are taken. Residents are likely to want to know about releases of plant pests or biological control organisms from motor vehicles or helicopters in their neighborhoods.

Although most people are not bothered by insects, biological control may be anathema to individuals with entomophobia. Although permit programs have no control over notifications given to populations near release sites, psychological impacts can be an indirect effect of permit issuance.

e. Noise

The effects of noise from the release procedures for organisms have been considered. Aircraft noise and ground release equipment noise occur for only short durations of time and at low frequencies of repetition, so that disturbances to humans from program actions are likely to be minimal and temporary. Noise from movement of plant pest and biological control organisms is not expected to be distinguishable from background noise or noise from other transportation.

f. Socioeconomics

People potentially affected by permit decisions to move or release plant pests may belong to any of several major social groups including agricultural producers (producers of host crops, home gardeners, organic farmers, and beekeepers), pesticide applicators, scientific researchers,

students, and residents. Many other groups may be indirectly affected; however, this discussion will be restricted to those groups immediately impacted. The permitting decision will result in both benefits and risks for people within these social groups.

The impact of a permitting decision on agricultural producers will be, for the most part, beneficial. Plant pests represent a threat to numerous crops by causing substantial losses of produce, income, and export markets. Pest losses could be most serious for small farmers and people dependent upon gardens for a substantial portion of their food. Permitting decisions allowing releases of plant pests usually occur within the context of developing pest control measures. Permit conditions serve as a way to ensure impacts from the releases of pests are minimized under the permit-specific conditions. In contrast, decisions to release biological control organisms are often directed at protecting crops and income, as well as to alleviate the need for (and cost of) uncoordinated farm-by-farm control programs. The use of biological control organisms may benefit organic growers who are unable to use chemical control measures (such as pesticides) in their crop production.

Movement of organisms often is by breeders, agricultural supply companies, and university researchers who are developing pest-resistant plant varieties that will ultimately decrease risks associated with pesticide use and the resultant residues in the food chain. These activities lead to improved crops available to consumers and livestock producers. Scientific research studying basic pest biology ultimately benefits society by increasing knowledge and allowing development of a wide variety of pest control measures. The movement of organisms for educational purposes benefits students by increasing awareness and opportunities for study of permitted organisms.

Biological control organisms may be adversely affected by pesticides. Growers relying on biological control organisms may lose their investment in this control measure and suffer crop losses if pesticides kill their released organisms. The weather and other factors may result in the ineffectiveness of biological control organisms in other years. Many of these organisms require time to increase populations to levels that are robust enough to affect the target species. The location where biological control organisms are released often determines the extent of suppressive effects observed on invasive host species. For these reasons, release of biological control organisms may not provide timely plant pest control in any given year.

g. Cultural and Visual Resources

The issuance of permits is expected to have minimal effect on cultural and scenic resources. Equipment (aircraft or trucks) used to release the organisms may affect those resources only to the extent that the activity or noise may disturb visitors to these resources. The potential effects of biological control on cultural resources would depend on the species-specificity of the controls, the relative contribution of nontarget species to the particular resource, and the effect on the species. Mortality of insects is not likely to directly affect cultural resources; however, adverse effects on plants could change the appearance of gardens. There may also be individuals who find certain nonnative invasive weeds to be desirable. For example, although strawberry guava in Hawaii is known to be invasive, some individuals prize its presence for its appearance and fruit. Any damage from biological control organisms could be viewed as damaging to the appearance of their property by these individuals. Permits for movement of organisms into biocontainment facilities are not expected to affect cultural and scenic resources because it would be exceedingly rare for inspected facilities to also be listed as historic or cultural resources.

4. Irreversible and Irretrievable Commitments of Resources

The irretrievable commitment of resources devoted to the development and maintenance of a highly skilled staff is vital to meet the ongoing need for APHIS' permitting decisions.

The PPB currently uses an established work flow within its electronic permitting system to review and evaluate permit applications to determine the plant pest risk and environmental consequences associated with the movement of a live plant pest, noxious weed, and/or soil into or through the United States. The PPB evaluation scientists determine if adequate safeguarding measures can be implemented and maintained to mitigate risks. The PPB has a staff of 20 employees (16 scientists and 4 support specialists). These employees have extensive education and received training to perform these highly specialized jobs. Scientists in the PPB develop pest data sheets that document the scientific basis for permit decisionmaking, in addition to documenting permitting decisions within each application's records.

The APHIS electronic permitting system used by the PPB is a capital information technology (IT) investment which involves an irretrievable commitment of agency resources. The system is used to issue the majority of permits and other documents (e.g., letters of denial, letters of permit cancellation, letters of no jurisdiction) and document the withdrawal of applications by the PPB. The efficiency of agency regulatory work for permitting increased dramatically by use of the electronic permitting system; more than 70 percent of applicants utilize this online resource to submit PPQ Forms 526 and 525 for permits. This increased use of

electronic databases by APHIS and other agencies is part of an irreversible trend. The electronic permitting system is also a repository of documentation that supports the authorization of containment facilities. Several USDA agencies and CBP use this system as a shared resource.

The agency analyzes the potential impact pertaining to releases of live plant pests, Federal noxious weeds, and soil into the environment in the context of NEPA. Numerous past and present permit issuance decisions are based on the outcome of these analyses and the subsequent publications of findings of no significant impact. Likewise, applicants commit considerable time and effort to seek issuance of permits for movement of these organisms and soil. Commitments of resources pertaining to these activities and to the policies that form the basis for permit decisions are irreversible and irretrievable.

Each movement of an organism or an associated commodity under permit constitutes an irreversible action. After a species of an organism is released into the environment, the organism and their progeny may not be retrieved. Movement of organisms and associated commodities involve actions that may irreversibly affect the environment. Although a permit may be canceled or amended by the PPB, each decision involves irreversible and irretrievable commitments of resources.

Regulatory permit policy pertaining to evaluation of biocontainment facilities was developed and established by the agency over the course of many years. To date, more than 3,100 facilities were inspected by APHIS personnel to determine if they are adequate to safely maintain permitted organisms. APHIS devoted considerable effort to establish an efficient and effective system of facility review. The regulated community has also invested considerable time and resources to meet APHIS' biocontainment facility requirements. These commitments of resources are irreversible and irretrievable.

5. Relationship to Other Federal and State Agency Actions

The completion of this EIS and preparation of a final record of decision does not ensure that any biocontainment facility will be approved, or that any release of any specific biological control organism may proceed; however, it does provide information about the potential cumulative environmental impacts that could be anticipated from these actions. Such information could be incorporated by reference into EAs for permit-specific movements and applications for releases. Similarly, this EIS does not ensure that any specific organisms will be excluded from permitting processes; however, it assumes that risks associated with each plant pest and biological control organism will be at an acceptable level. There are various cooperating agencies that play a role in the permitting process that may lead to issuance or denial of a given application. The primary agencies whose actions affect the permitting decisions are—

- the U.S. Department of the Interior's Fish and Wildlife Service (FWS),

- the U.S. Department of Homeland Security's Customs and Border Patrol (CBP), and

- State plant health regulatory authorities (for State of destination for the organism or soil requested to be moved/released).

Each of these agencies provides important information to ensure that APHIS makes informed decisions before issuing any permits. The primary function of FWS in the permitting process is to provide information about threatened and endangered species through section 7 consultation. This serves to ensure that any movement of plant pests and associated protection measures will preclude adverse effects to any listed species. CBP personnel monitor movement of people and goods across borders. CBP officers verify shipments of live plant pests have the proper paperwork and certification of permit issuance before allowing importation from other countries. This includes inspection of paperwork for hand-carry of all permitted organisms by researchers. In addition, they inspect the packaging material to verify package integrity during movement for importation. There is an ongoing effort to ensure the clearance process for properly certified shipments is completed thoroughly and efficiently. The State plant health regulatory authorities are consulted when there are permit applications for movement to their State, to seek information about any ongoing quarantine or eradication program for the species, and to obtain any specific prohibition on transport of that species into the State. Cooperation with these agencies is essential to ensuring a smooth permitting process for the movement of the plant pests.

In addition to agencies that cooperate in the review of an application for a permit, several Federal agencies routinely apply for permits for their program actions. Some APHIS programs use biological control organisms and sterile insect technique in their actions against various pest species. Some divisions of USDA–ARS develop and test plant material for resistance to plant pests, or develop biological control organisms for various weed and pest control applications. Most applications relate to agricultural issues; however, some applications of biological control technology are applied to weed control programs for border security for the U.S. Department of Homeland Security's CBP. The National Aeronautics and Space Administration periodically applies for permits for interstate movement to launch sites and post-recovery research locations for the insects, fungi, and spiders used in their experiments. There also may be permit applications from State agencies to move or release a biological control organism. Each of these programs at the respective

agencies is required to apply for a permit for movement of the plant pest species.

6. Consultative Processes Related to Permitting

The current regulations do not place restrictions on those who may be consulted by the permit scientist in their review of risks related to movement of plant pests. The consultants may include Government officials and, "any other qualified governmental or private research laboratory, institution, or individual" (7 CFR § 330.202 (a)). There are a number of consultative processes that are integral to completing review of an application for a permit. The consultative processes most frequently invoked as part of the permitting process are as follows:

- Consultation with State plant health regulatory authorities for the State of destination for movement of an organism;
- Technical Advisory Group (TAG) review of requests for classical biological control of weeds;
- North American Plant Protection Organization (NAPPO);
- Section 7 Consultation with U.S. Department of the Interior's FWS and/or the Department of Commerce's NMFS; and
- Convention on International Trade in Endangered Species (CITES).

These consultative processes provide information to inform the decisionmaker whether to issue or deny a permit by providing either recommendations or clarifying mitigations designed to preclude adverse effects (protective measures or other mandatory regulatory requirements).

Consultation with State plant health regulatory authorities in the State of destination for movement of an organism ensures information about potential movement and releases is shared in a timely manner so their concerns can be expressed. The State may have an ongoing quarantine or eradication program for the plant pest to be released, or the release could affect other State programs. Each State may have a list of species prohibited entry. Parts of certain States have areas of land isolated by rough topography or islands that require special protection. In particular, the State of Hawaii recognizes a number of potentially invasive species that are denied import from other countries, and denied entry from the continental United States. Ensuring species on their lists are not issued permits for movement into these States is important to meet compliance and containment requirements.

There are two review groups that provide input and recommendations to APHIS regarding the decision to release or not release a biological control

organism—the TAG and a review group that is part of NAPPO. As described in Chapter I.C.4.g (Purpose and Need) section C.4.g, the TAG consists of individuals who form an interagency group that reviews information on petitions for release of biological control organisms of weeds, and make recommendations to APHIS concerning their first-time release. Their recommendations are considered carefully by APHIS decisionmakers, but this does not guarantee that the TAG recommendations will be followed. There may be other policy, legal, or plant pest issues that are considered critical in the ultimate decision.

The other review group, which is a part of NAPPO, centers its review on the regional standards for phytosanitary measures for Canada, Mexico, and the United States. In particular, this review adheres to RSPM No. 12, "Guidelines for Petition for First Release of Exotic Entomophagous Biological Control Agents" (NAPPO, 2015b). The NAPPO petition process is similar to that of TAG's review of weed biological control organisms, but is limited to entomophagous biological control. There have, however, been some petitions for entomopathogenic biological control organisms reviewed through the same NAPPO petition process (e.g., *Nosema* for gypsy moth control, and a pathogenic nematode for control of *Sirex noctilio*).

There are two petition reviews related to protection of endangered species that result in consultation. The first involves ESA section 7 consultation with FWS regarding considerations for potential permit releases. Compliance with this act involves an analysis of the impact of Federal action (permit issuance) upon listed species. Under ESA, animal and plant species and critical habitat must be specifically listed in order to gain protection. Federal agencies that propose actions which could have an effect on threatened and endangered species that are listed or proposed to be listed, or on designated or proposed critical habitat, must prepare biological evaluations for those species potentially affected by their programs and actions. FWS provides a concurrence letter or biological opinion regarding each biological evaluation prepared by APHIS for permits for release of plant pests. (Compliance with ESA is discussed in greater detail earlier in this chapter in sections C.1.b. and C.3.a.)

The second review related to endangered species involves international review under the Convention on International Trade in Endangered Species (CITES). Compliance with U.S. agreements under CITES is facilitated through PPQ Form 621 permits. This compliance is critical to permit applications for importation of plant pests.

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EIS Responsibility: EIS analyst—wrote parts of the executive summary and introductions, and contributed to sections of the four chapters and appendices. Responsibility for coordination and team management of documentation. Organized the administrative record.

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EIS Responsibility: Project manager for the draft EIS—prepared the endangered species sections of this EIS and some sections in chapters 2, 3, and 4.

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applications for plant pests and genetically engineered organisms, preparation of EAs, facilitation of TAG reviews, and correspondence with petitioners for first time release of proposed nonindigenous weed biological control organisms.

EIS Responsibility: Project coordinator for PPB scientists. Wrote parts of permit scoping in chapter 1 in areas of permit expertise and provided guidance on TAG templates in appendices. Responsible for coordination of efforts between PPB scientists and EIS project manager. Responsible for review of entire draft EIS document and response to comments

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EIS Responsibility: EIS Analyst—wrote parts of chapters 1 and 4.

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EIS Responsibility: EIS Analyst—wrote parts of the Executive Summary and chapter 4.

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EIS Responsibility: EIS Analyst—wrote parts of chapters 1 and 2.

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Appendix E. Associated Federal Register Notices

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Proposed Rules

Federal Register
Vol. 74, No. 201
Tuesday, October 20, 2009

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 330

[Docket No. APHIS-2008-0076]

Environmental Impact Statement; Movement of Plant Pests, Biological Control Organisms, and Associated Articles

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service intends to prepare an environmental impact statement relative to proposed regulatory requirements that are being developed for the movement of plant pests, biological control organisms, and associated articles. This notice identifies potential issues and alternatives that will be studied in the environmental impact statement and requests public comment to further delineate the scope of those issues and alternatives.

DATES: We will consider all comments that we receive on or before November 19, 2009.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to (*http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0076*) to submit or view comments.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS-2008-0076, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2008-0076.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at (*http://www.aphis.usda.gov*).

FOR FURTHER INFORMATION CONTACT: Dr. David A. Bergsten, APHIS Interagency NEPA Contact, Environmental Services, PPD, APHIS, 4700 River Road, Unit 149, Riverdale, MD 20737-1238; (301) 734-6103.

SUPPLEMENTARY INFORMATION:

Background

The purpose of the regulations in "Subpart —Movement of Plant Pests" (7 CFR 330.200 through 330.212, referred to below as the regulations) is to prevent the dissemination of plant pests within the United States by regulating their importation and interstate movement.

The Animal and Plant Health Inspection Service (APHIS) is planning to revise its regulations regarding the movement of plant pests. APHIS intends to prepare an environmental impact statement (EIS) analyzing the potential environmental impacts associated with proposed regulatory requirements for movement not only of plant pests, but also of biological control organisms, and associated articles.

Under the Plant Protection Act (7 U.S.C. 7701 *et seq.*, referred to below as the Act) the Secretary of Agriculture has broad authority to carry out operations or measures to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests. Section 411(a) of the Act provides that "no person shall import, enter, export, or move in interstate commerce any plant pest, unless the importation, entry, exportation, or movement is authorized under general or specific permit and is in accordance with such regulations as the Secretary may issue to prevent the introduction of plant pests into the United States." Moreover, section 412(a) of the Act provides that the Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of, among other things, any biological control organism, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or the dissemination within the United States of a plant pest or noxious weed.

Accordingly, APHIS has the authority to regulate not only plant pests, but also biological control organisms, noxious weeds, and associated articles. APHIS is therefore considering revising the regulations to establish provisions for the movement and environmental release of biological control organisms and associated articles. APHIS is also considering revising the regulations for the movement of soil, and establishing regulations governing the biocontainment facilities in which plant pests, biological control organisms, and associated articles are held. The impacts associated with these changes to the regulations will also be analyzed in a programmatic EIS.

In addition to establishing a regulatory framework for the movement of new organisms and articles in a manner that protects U.S. agriculture, these proposed regulations would help clarify the existing requirements for the importation and domestic movement of plant pests. APHIS may also consider including within the proposed regulations other mitigating measures with the potential to equally reduce pest risk. We are requesting public comment to help us identify or confirm potential alternatives and environmental issues that should be examined in the EIS. We have identified three broad alternatives that we plan to consider in the EIS, as follows:

- Take no action. This would be characterized as no change in the existing regulations that apply to the movement of plant pests (while not contributing to the further mitigation of pest risk, the analysis of the no action alternative provides a baseline and is required by the National Environmental Policy Act and its implementing regulations).
- Revise requirements for movement of plant pests consistent with the scope of the Plant Protection Act (preferred alternative). This would be characterized by amendment or revision of the plant pest regulations to also cover biological control organisms and associated articles. It would also include revisions to the regulations for the movement of soil and the establishment

of regulations for biocontainment facilities.

• Implement a comprehensive risk reduction program (more expansive regulations to address specific risk categories). This would be characterized as a broad risk mitigation strategy that could involve various options such as increased inspection, regulations specific to a certain organism or group of related organisms, or extensive biocontainment requirements. While not the preferred alternative at this time, the risk mitigation strategy considered within this alternative could provide the basis at some point for future Agency regulatory actions, either to establish a new and more appropriate regulatory framework for the movement of plant pests, biological control organisms, and associated articles, or to augment the existing regulations with more effective mitigation measures to address the risk of such movement.

We will examine the potential effects on the human environment of each alternative. We are also interested in comments that identify other issues that should be examined in the EIS. Potential issues include other new mitigation measures, logistical considerations, environmental regulations and constraints, and harmonization of regulatory efforts.

The EIS will be prepared in accordance with: (1) The National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Comments regarding the proposed scope of the EIS are welcome and will be considered fully. When APHIS has completed a draft EIS, a notice announcing its availability and an invitation to comment on it will be published in the **Federal Register**.

Done in Washington, DC, this 14th day of October, 2009.

Kevin Shea

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E9–25184 Filed 10–19–09: 8:45 am]

BILLING CODE: 3410–34–S

FEDERAL ELECTION COMMISSION

11 CFR Part 100

[Notice 2009–22]

Definition of Federal Election Activity

AGENCY: Federal Election Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Election Commission seeks comments on proposed changes to its rules regarding the definitions of "voter registration activity" and "get-out-the-vote activity" under the Federal Election Campaign Act of 1971, as amended. These proposed changes are in response to the decision of the U.S. Court of Appeals for the District of Columbia Circuit in *Shays* v. *FEC*. The Commission has made no final decision on the issues presented in this rulemaking. Further information is provided in the supplementary information that follows.

DATES: Comments must be received on or before November 20, 2009. The Commission will hold a hearing on these proposed rules on Wednesday, December 16, 2009 at 9:30 a.m. and, if necessary, Thursday, December 17, 2009 at 9:30 a.m. Anyone wishing to testify at the hearing must file written comments by the due date and must include a request to testify in the written comments.

ADDRESSES: All comments must be in writing, addressed to Ms. Amy L. Rothstein, Assistant General Counsel, and submitted in either electronic, facsimile or hard copy form. Commenters are strongly encouraged to submit comments electronically to ensure timely receipt and consideration. Electronic comments should be sent to *FEAShays3@fec.gov*. If the electronic comments include an attachment, the attachment must be in Adobe Acrobat (.pdf) or Microsoft Word (.doc) format. Faxed comments should be sent to (202) 219–3923, with hard copy follow-up. Hard copy comments and hard copy follow-up of faxed comments should be sent to the Federal Election Commission, 999 E Street, NW., Washington, DC 20463. All comments must include the full name and postal service address of the commenter or they will not be considered. The Commission will post comments on its web site after the comment period ends. The hearing will be held in the Commission's ninth floor meeting room, 999 E Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ms. Amy L. Rothstein, Assistant General Counsel, or Attorneys Mr. David C. Adkins or Mr. Neven F. Stipanovic, 999 E Street, NW., Washington, DC 20463, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: The Bipartisan Campaign Reform Act of 2002 [1] ("BCRA") contained extensive and detailed amendments to the Federal Election Campaign Act of 1971, as amended, 2 U.S.C. 431 *et seq.* ("the Act"). The Commission promulgated a number of rules to implement BCRA, including rules defining the terms "voter registration activity" and "get-out-the-vote activity" ("GOTV activity") at 11 CFR 100.24(a). The Court of Appeals for the District of Columbia Circuit found aspects of these rules invalid in *Shays* v. *FEC*, 528 F.3d 914 (D.C. Cir. 2008) ("*Shays III Appeal*"). The Commission seeks comment on proposed changes to the rules at 11 CFR 100.24 to implement the *Shays III Appeal* decision.

I. Background

A. BCRA

The Act, as amended by BCRA, and Commission regulations provide that a State, district, or local committee of a political party must pay for certain "Federal election activities" with either entirely Federal funds [2] or, in other instances, a mix of Federal funds and "Levin funds." [3] *See* 2 U.S.C. 441i(b); 11 CFR 300.32. The Act identifies four types of activity that are subject to these funding restrictions, including "voter registration activity"—Type I Federal election activity—and GOTV activity—Type II Federal election activity. *See* 2 U.S.C. 431(20)(A)(i) and (ii); 441i(b); 11 CFR 100.24(a)(2) and (3).[4]

Application of BCRA's Federal election activity funding restrictions for Types I and II Federal election activity is conditioned upon the timing of the activity. Voter registration activity (Type

[1] Pub. L. 107–155, 116 Stat. 81 (2002).

[2] "Federal funds" are funds subject to the limitations, prohibitions, and reporting requirements of the Act. *See* 11 CFR 300.2(g).

[3] "Levin funds" are funds raised and disbursed by State, district, or local party committees pursuant to certain restrictions. *See* 2 U.S.C. 441i(b); *see also* 11 CFR 300.2(i).

[4] In addition to GOTV activity, Type II Federal election activity also includes "voter identification" and "generic campaign activity." *See* 2 U.S.C. 431(20)(A)(ii); 11 CFR 100.24; 100.25. Types III and IV Federal election activity are outside the scope of this rulemaking and are not discussed. They pertain to public communications that refer to a clearly identified Federal candidate and promote, support, attack or oppose a candidate for Federal office (Type III), and services provided by an employee of a State, district, or local committee of a political party who spends more than 25 percent of his or her compensated time on activities in connection with a Federal election (Type IV). Types I and II Federal election activity may be funded with a combination of Federal and Levin funds; Types III and IV Federal election activity must be funded entirely with Federal funds.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 318, 319, 330, and 352

[Docket No. APHIS–2008–0076]

RIN 0579–AC98

Plant Pest Regulations; Update of Provisions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; withdrawal and reproposal.

SUMMARY: We are proposing to revise our regulations regarding the movement of plant pests. We are proposing criteria regarding the movement and environmental release of biological control organisms, and are proposing to establish regulations to allow the importation and movement in interstate commerce of certain types of plant pests without restriction by granting exceptions from permitting requirements for those pests. We are also proposing to revise our regulations regarding the movement of soil. This proposed rule replaces a previously published proposed rule, which we are withdrawing as part of this document. This proposal would clarify the factors that would be considered when assessing the risks associated with the movement of certain organisms and facilitate the movement of regulated organisms and articles in a manner that also protects U.S. agriculture.

DATES: We will consider all comments that we receive on or before March 20, 2017.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0076.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2008–0076, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0076* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Colin D. Stewart, Assistant Director; Pests, Pathogens, and Biocontrol Permits Branch, Plant Health Programs, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737–1236; (301) 851–2237.

SUPPLEMENTARY INFORMATION:

Background

Under the Plant Protection Act (7 U.S.C. 7712 *et seq.,* referred to below as the PPA or the Act), the Secretary of Agriculture has authority to carry out operations or measures to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests. Section 7711(a) of the Act provides that ''no person shall import, enter, export, or move in interstate commerce any plant pest, unless the importation, entry, exportation, or movement is authorized under general or specific permit and in accordance with such regulations as the Secretary may issue to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States.'' The Act gives the United States Department of Agriculture (USDA) the flexibility to respond appropriately to a wide range of needs and circumstances to protect American agriculture against plant pests. The Act defines a plant pest as ''any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: (A) A protozoan; (B) A nonhuman animal; (C) A parasitic plant; (D) A bacterium; (E) A fungus; (F) A virus or viroid; (G) An infectious agent or other pathogen; (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.''

In addition, section 412(a) of the Act provides that the Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of, among other things, any biological control organism if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States. The Act defines a biological control organism as ''any enemy, antagonist, or competitor used to control a plant pest or noxious weed.''

The purpose of the regulations in ''Subpart—Movement of Plant Pests'' (7 CFR 330.200 through 330.212) and ''Subpart—Movement of Soil, Stone, and Quarry Products'' (7 CFR 330.300 through 330.301) is to prevent the dissemination of plant pests into the United States, or interstate, by regulating the importation and interstate movement of plant pests, soil, stone, and quarry products.

These regulations were issued by the Animal and Plant Health Inspection Service (APHIS) under the authority provided by, among other statutes, the Department of Agriculture Organic Act of 1944, as amended (7 U.S.C. 147a), and the Federal Plant Pest Act, as amended (7 U.S.C. 150aa through 150jj), both of which were superseded and repealed by the PPA. Most of the provisions of the PPA regarding the importation and movement of plant pests were modeled on or directly derived from these two Acts; thus, the enactment of the PPA did not necessitate a major revision of the subpart. However, the PPA did contain provisions that clarified the authority in the earlier Acts regarding, among other things, our ability to regulate the importation and interstate movement of biological control organisms, as well as noxious weeds and associated articles.

Accordingly, on October 9, 2001 (66 FR 51340–51358, Docket No. 95–095–2), we published in the **Federal Register** a proposed rule which would have revised the plant pest regulations. Among other proposed provisions, it would have established a notification process that could be used as an alternative to the permitting system, provided for the environmental release of organisms for the biological control of weeds, and updated the text of the subpart to reflect the provisions of the PPA.

We solicited comments for 60 days ending December 10, 2001. We received 1,332 comments by that date. They were from State Departments of Agriculture, a State fish and wildlife agency, universities, plant societies, biocontrol organizations, USDA's Forest Service and Agricultural Research Service, the U.S. Environmental Protection Agency (EPA), zoological associations, the World Trade Organization, pharmaceutical groups and biological supply companies, wildlife protection and conservation groups, trade organizations, butterfly breeders and associations, elementary schools, and private citizens.

The majority of the comments that we received were from schools and students who requested that we continue to allow the environmental release of Monarch butterflies as part of a learning curriculum. Some of these commenters also requested that we continue to allow the environmental

release of Monarch butterflies for weddings and other ceremonies.[1]

We also received comments that addressed the proposed rule both generally and in regard to its specific provisions. Commenters often requested clarification regarding or suggested modification to several of the rule's provisions, but were, on the whole, generally supportive of the proposed rule. Accordingly, based on our evaluation of the comments that we received, we planned to issue a final rule.

However, the events of September 11, 2001, led to a further evaluation of our proposal to determine whether the proposed provisions had sufficient safeguards governing our permitting process. Specifically, we evaluated whether an aspect of our proposal, which would have authorized the importation of regulated organisms without prior issuance of a permit, provided that the party receiving the organisms had entered into a compliance agreement with APHIS, could serve as a potential venue for bioterrorism. We also temporarily suspended issuance of new plant pest permits.

In addition, on March 31, 2003, USDA's Office of the Inspector General (OIG) issued an audit of APHIS' permitting programs. Among other things, the audit examined APHIS' issuance of plant pest permits, and its administration of the permitting process. The audit suggested that we implement ePermits, a more thorough and technologically advanced permitting database than that used at the time, that we discontinue our practice at the time of issuing "blanket" permits to individuals or organizations to move plant pests and biological control organisms in favor of specific permits for each movement of a regulated organism, that we require more thorough documentation of an organism's intended use on each permit application, that we develop risk-based criteria for deciding whether or not to issue a permit for a particular movement, that we inspect the destinations listed on permit applications more regularly to evaluate their suitability for the organisms held onsite, and that we establish clear protocols, with an adequate degree of APHIS oversight, regarding the disposal of organisms once a permit expires. A 2007 followup OIG audit again encouraged us to fully implement ePermits, particularly at ports of entry into the United States.

Although APHIS has not substantively revised the regulations in the subpart since the promulgation of the PPA and the release of the OIG audits, these audit reports have informed Agency decisions regarding our regulation of the movement of plant pests, biological control organisms, and associated articles.

In this proposal, we are withdrawing our 2001 proposed rule and replacing it with an alternative proposal. This proposal retains several of the provisions of the 2001 proposal. For example, the conditions under which we would consider an organism a plant pest, and thus regulated by the subpart, remain similar to those of the 2001 proposal. However, this proposal also removes or modifies other provisions of the 2001 proposal. For example, we have removed provisions that would have authorized the movement of regulated organisms through a process consisting of compliance agreements and notification of movement.

Additionally, this proposal also incorporates new provisions that were not contained in the 2001 proposed rule but that would codify procedures that we have identified as best practices since that time but not yet added to the regulations.

The most significant changes in this new proposal are:

- We are proposing to establish criteria for the movement and environmental release of both biological control organisms of noxious weeds and those of plant pests; and
- We are proposing to remove "Subpart—Movement of Soil, Stone, and Quarry Products" and would instead regulate these articles in a subpart titled "Subpart—Movement of Plant Pests, Biological Control Organisms, and Associated Articles."

The full text of the proposed regulations appears in the rule portion of this document. Our discussion of the proposed provisions follows.

Definitions

In addition to our proposed revision of "Subpart—Movement Plant Pests" and removal of "Subpart—Movement of Soil, Stone, and Quarry Products," we would also revise § 330.100, "Definitions," of "Subpart—General Provisions," to incorporate the applicable new definitions provided by the PPA and to update or eliminate some of the definitions currently provided in that section.

From the PPA, we would add definitions for the terms *article, biological control organism, enter (entry), export (exportation), import (importation), noxious weed, plant,* and *plant product;* and we would replace the current definitions of *move (moved and movement), permit, person, plant pest,* and *State* with the definitions provided for those terms in the PPA. However, regarding the definition of *permit,* although the PPA definition mentions the issuance of oral permits, our proposed definition does not. For the purposes of the plant pest regulations, oral permits would not provide a reliable means of verifying that a permittee was aware of the permit conditions at the time he or she was issued the permit, and would, we believe, adversely affect APHIS' ability to ensure appropriate compliance and enforcement of our regulatory requirements.

We would also add definitions for *Animal and Plant Health Inspection Service (APHIS), biocontainment facility, EPA, hand-carry, interstate movement, living, permittee, responsible individual, secure shipment, sterilization (sterile, sterilized), taxon (taxa), transit,* and *U.S. Customs and Border Protection (CBP).* We will first discuss what we mean by the term *taxon (taxa).* We will then discuss, in alphabetical order, the definitions of the other new terms that we are proposing to add to the regulations.

We would define *taxon (taxa)* as: "Any recognized grouping or rank within the biological nomenclature of organisms, such as class, order, family, genus, species, subspecies, pathovar, biotype, race, forma specialis, or cultivar." This proposed definition is based on the International Plant Protection Convention's (IPPC's) Glossary of Phytosanitary Terms,[2] which uses taxon, at various points, in reference to family, species, and subspecies.

We would define the term *Animal and Plant Health Inspection Service (APHIS)* as: "The Animal and Plant Health Inspection Service of the United States Department of Agriculture."

We would define the term *biocontainment facility* as: "A physical structure, or portion thereof,

[1] Under this proposed rule, which withdraws our 2001 proposal, we would authorize the issuance of permits for the environmental release of Monarch butterflies in accordance with current practices. Under these practices, permits issued to permittees who reside east of the Rocky Mountains would authorize the environmental release of Monarch butterflies east of the Rockies, while those issued for permittees who reside west of the Rocky Mountains would authorize the environmental release of Monarch butterflies west of the Rockies. This is because there are two distinct ecological ranges for Monarchs in the United States, with each terminating at the Rocky Mountains.

[2] International Standard for Phytosanitary Measures (ISPM) Number 5. To view this and other ISPMS, go to *https://www.ippc.int/en/core-activities/standards-setting/ispms/#publications.*

constructed and maintained in order to contain plant pests, biological control organisms, or associated articles."

We would define the term *EPA* as: "The Environmental Protection Agency of the United States."

We would define the term *hand-carry* as: "Importation of an organism that remains in one's personal possession and in close proximity to one's person." Our requirements governing the movement of plant pests by baggage, currently found in § 330.212, are commonly referred to as the "hand-carry" regulations; we are proposing to revise these requirements.

We would define the term *interstate movement* as: "Movement from one State into or through any other State; or movement within the District of Columbia, Guam, the U.S. Virgin Islands, or any other territory or possession of the United States."

We would define the term *living* as: "Viable or potentially viable." We are including "potentially viable" within our definition of *living* because most viruses and retroviruses of plants and plant products cannot grow or reproduce outside of a host cell; however, once inserted into the cell, they are capable of both growth and self-replication, and, over time, exhibit pathogenic effects. Because of this potential for both growth and self-replication, it is generally our policy to consider such viruses living plant pests, and to require a permit for their importation, interstate movement, transit, or continued curation.

We would define the term *permittee* as: "The person to whom APHIS has issued a permit in accordance with this part and who must comply with the provisions of the permit and the regulations in this part."

We would define the term *responsible individual* as: "The individual who a permittee designates to oversee and control the actions taken under a permit issued in accordance with this part for the movement or curation of a plant pest, biological control organism, or associated article. For the duration of the permit, the individual must be physically present during normal business hours at or near the location specified on the permit as the ultimate destination of the plant pest, biological control organism, or associated article, and must serve as a primary contact for communication with APHIS. The permittee may designate him or herself as the responsible individual. The responsible individual must be at least 18 years of age. In accordance with section 7734 of the PPA, the act, omission, or failure of any responsible individual will also be deemed the act, omission, or failure of a permittee."

Historically, we have only issued permits for the movement of plant pests, biological control organisms, and associated articles to individuals. However, as provided for in the definition of *permittee,* we would allow corporate entities to obtain permits under the revised regulations. This change will allow for better tracking and communication regarding a permit or permit application, and will also make it clear that the corporation as a whole is responsible for the permit. In such instances, we believe that it is of paramount importance that the permittee specifies a person whom APHIS may contact regarding the actions authorized under the permit who has first-hand knowledge of these actions. The responsible individual would fulfill this role.

We anticipate that, if this rule is finalized, we would still issue a significant number of permits to individuals, rather than corporate entities. We expect that, for the majority of such permits, the permittee would wish to designate him or herself as the responsible individual; therefore, the definition of *responsible individual* would allow for such designation.

Finally, Section 7734 of the PPA provides that a person will be held liable for the acts, omissions, and failures of an agent acting for that person, as long as the agent is acting within the scope of his or her office. Responsible individuals would be agents of the permittee pursuant to this section of the PPA.

We would define the term *secure shipment* as: "Shipment of a regulated plant pest, biological control organism, or associated article in a container or a means of conveyance of sufficient strength and integrity to prevent leakage of contents and to withstand shocks, pressure changes, and other conditions incident to ordinary handling in transportation."

We would define the term *sterilization (sterile, sterilized)* as: "A chemical or physical process that results in the death of all living organisms on or within the article subject to the process. Examples include, but are not limited to, autoclaving and incineration."

Note that, for the purposes of this subpart, the term sterilization does not refer to techniques that neutralize an organism by rendering it incapable of sexual reproduction. We recognize that this alternate meaning of the term "sterilization" might be more common within the regulated community, but believe that it is clear from the manner in which we would use the term in the revised subpart that it would have a different meaning within these regulations.

We would define the term *transit* as: "Movement from and to a foreign destination through the United States." This definition would replace a definition currently in the regulations, *through the United States,* which we define as: "From and to places outside the United States."

We would define the term *U.S. Customs and Border Protection (CBP)* as: "U.S. Customs and Border Protection within the Department of Homeland Security." This definition would replace the now outdated definition of *Customs* in the current regulations.

In addition, we would substantively revise the definition of *soil.* We currently define *soil* as: "The loose surface material of the earth in which plants grow, in most cases consisting of disintegrated rock with an admixture of organic material and soluble salts." We would redefine *soil* as: "The unconsolidated material from the earth's surface that consists of rock and mineral particles and that supports or is capable of supporting biotic communities." This definition aligns with the current scientific understanding of soil, and would resolve ambiguities in the current definition that could be construed to suggest that soil includes consolidated or sterile matter that does not present a risk of harboring plant pests or noxious weeds. (For purposes of the regulations, it does not.) We would also remove the definition of *earth,* "the softer matter composing part of the surface of the globe, in distinction from the firm rock, and including the soil and subsoil, as well as finely divided rock and other soil formation materials down to the rock layer," from the regulations.

We would remove the definition of *Plant Protection Act.* The Act is cited in the authority citation for part 330, and we do not believe it is necessary to define it in the regulations.

We would make nonsubstantive editorial changes to the definitions of *administrative instructions, Administrator, Department, Deputy Administrator, inspector, means of conveyance, owner,* and *Plant Protection and Quarantine Programs.*

Finally, we would retain, without modification, the existing definitions of *garbage, regulated garbage,* and *shelf-stable.*

Titles of the Part and Subpart

Currently, the title of part 330, "Federal Plant Pest Regulations; General; Plant Pests; Soil, Stone, and Quarry Products; Garbage," reflects the

titles of its four subparts. As mentioned above, we are proposing to revise the second subpart, currently titled "Subpart—Movement of Plant Pests," to clarify that it regulates the movement not only of plant pests, but also of biological control organisms and associated articles, including soil. Since we would now regulate soil within that subpart, we would remove and reserve the third subpart, "Subpart—Soil, Stone, and Quarry Products."

For this reason, we would also update the title of the second subpart. As amended, it would now be titled "Subpart—Movement of Plant Pests, Biological Control Organisms, and Associated Articles."

As a result of these proposed revisions, we would also revise the title of the part. It would now be titled: "Federal Plant Pest Regulations; General; Plant Pests, Biological Control Organisms, and Associated Articles; Garbage."

Scope and General Restrictions (§ 330.200)

The proposed regulations would begin by establishing the scope of the revised subpart. Paragraph (a) would state that no person shall import, move interstate, transit, or release into the environment plant pests, biological control organisms, or associated articles, unless the importation, interstate movement, transit, or release into the environment of the plant pests, biological control organisms, or associated articles is:

- Authorized under an import, interstate movement, or continued curation permit issued in accordance with proposed § 330.201;
- Authorized in accordance with other APHIS regulations in 7 CFR chapter III;
- Explicitly granted an exception or exemption in the revised subpart from permitting requirements.
- Authorized under a general permit issued by the Administrator.

By "authorized in accordance with other APHIS regulations in 7 CFR chapter III," we mean that certain movements of plant pests or associated articles are regulated under other APHIS regulations in title 7. For example, the transit of a plant pest through the United States would require a permit issued in accordance with § 352.5 of the plant quarantine safeguard regulations in 7 CFR part 352, and the interstate movement of regulated associated articles of domestic quarantine pests (*e.g.,* host articles of pine shoot beetle or Asian citrus psyllid) normally require certificates or limited permits issued in accordance with their respective subparts in the domestic quarantine notice regulations of 7 CFR part 301.

We discuss the exemptions from permitting requirements that we are proposing to grant for certain categories of biological control organisms in the discussion under the heading "*Biological control organisms (§ 330.202),*" and the exceptions from permitting requirements that we are proposing to grant for certain plant pests in the discussion under the heading "*Exceptions to permitting requirements for the importation or interstate movement of certain plant pests (§ 330.204).*"

Finally, to date, we have only issued specific permits, that is, permits issued to specific persons, for the interstate movement of plant pests. However, pursuant to section 7711 of the PPA, the Administrator may also issue general permits, that is, general authorizations, for the importation or interstate movement of plant pests.

In recent years, we have contemplated issuing a general, Web-based permit for the interstate movement of certain plant pests that we regard to be low-risk unless they are moved into certain areas of the United States, rather than specific permits for the movement of these pests. If we finalize proposed paragraph (a) of § 330.200 and decide to issue such a permit, we would announce the existence, location, and content of this general permit through a notice in the **Federal Register**.

Paragraph (b) of § 330.200 would specify the types of plant pests that we would regulate under the revised subpart. The paragraph would state that, for the purposes of the subpart, we would consider an organism to be a plant pest if the organism either directly or indirectly injures, causes damage to, or causes disease in a plant or plant product, or if the organism or part is an unknown risk to plants or plant products, but is similar to an organism known to directly or indirectly injure, cause damage to, or cause disease in a plant or plant product.

This paragraph, which is not found in the current regulations, is similar to the criteria for designating an organism a plant pest that were contained in our 2001 proposal. We have, however, made two changes to those criteria.

First, while our 2001 proposal would have designated certain organisms as plant pests if they directly or indirectly adversely affected plants, plant parts, or plant products, in this proposed rule, we would designate these organisms as plant pests if the organisms directly or indirectly injure, cause damage to, or cause disease in a plant or plant product. These latter criteria are based on the definition of *plant pest* found in the PPA, and have been our framework in recent years for determining whether an organism is a plant pest.

We would also expand the scope of our 2001 proposal so that we may consider organisms of an unknown risk to plants or plant products to be plant pests, provided that the organisms are similar to an organism known to directly or indirectly injure, cause damage to, or cause disease in a plant or plant product.

In our 2001 proposal, we did propose that organisms of an unknown risk to plants or plant products would require a permit, but we would have designated them regulated organisms rather than plant pests. We also stated that permitting conditions for such organisms would be aimed primarily at affording us an opportunity to identify and deal with the organisms with some initial degree of regulatory oversight, in order to prevent the dissemination of plant pests into or within the United States. We thus framed permitting requirements for such organisms as a necessary stopgap measure pending positive identification of the organism and an assessment of the organism's potential risk to plants and plant products.

However, since 2001, there have been numerous occasions when applicants have requested authorization to import organisms that cannot readily be identified to the species level for a significant portion of their lifespans, but that may be plant pests. For example, we have issued several plant pest permits for the importation of larval scarabs. Before becoming mature, all scarabs are morphologically similar to one another and exhibit similar feeding patterns, but are not plant pests. However, once mature, certain scarab species are plant pests. In order to take this potential for future effects on plants, plant parts, and plant products into consideration, in issuing a permit for any scarab grub, we have considered it to be a plant pest, and tailored permitting and containment requirements accordingly.

Paragraph (c) of § 330.200 would specify the types of biological control organisms that we would regulate under the revised subpart. Although the PPA defines a biological control organism as "any enemy, antagonist, or competitor used to control a plant pest or noxious weed," practically speaking, we have only required permits for certain types

of biological control organisms since the PPA was promulgated.[3] These are:

- Invertebrate predators and parasites (parasitoids) used to control invertebrate plant pests,
- Invertebrate competitors used to control invertebrate plant pests,
- Invertebrate herbivores used to control noxious weeds,
- Microbial pathogens used to control invertebrate plant pests,
- Microbial pathogens used to control noxious weeds, and
- Microbial parasites used to control plant pathogens.

Regarding these types of biological control organisms, we recognize that biological control organisms used to control noxious weeds are also plant pests, insofar as they injure, cause damage to, or cause disease in plants. However, since this effect is desirable and ultimately beneficial to other plants, plant parts, and plant products, it has been our policy to draft permitting conditions for the movement and environmental release of these organisms in a manner that encourages these effects, unless we have reason to believe that the organisms may also have plant pest effects on non-target plants or plant products.

As noted in the previous paragraphs, there are some types of biological control organisms for which we have not historically issued permits. However, there may be times when there would be a risk-based need to regulate the importation or interstate movement of an organism that falls within the PPA's definition of a *biological control organism,* but does not fall into any of the types of organisms listed above. For example, if a microbial parasite that has not previously been evaluated is put forth for the control of pathogenic fungi, it would not fall within the above categories, but could be an organism we would wish to regulate out of concern of the possibility of effects on non-target plants, such as fungi without phytopathogenic properties. To this end, paragraph (c) would also provide that other types of biological control organisms could be regulated under the revised subpart, as determined by APHIS. This determination would typically be on a case-by-case basis, and would be based on a permit application for movement of an organism which did not belong to any of the above types, but for which the Administrator determined it necessary to exercise a degree of regulatory oversight in order to prevent the introduction of a plant pest into the United States or the dissemination of a plant pest within the United States.

Paragraph (d) would exempt biological control organism products that EPA has issued experimental use permits for or that EPA has registered as microbial pesticide products having outdoor uses from regulatory oversight under the revised subpart. Under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*, FIFRA), EPA regulates certain biological control organisms (eukaryotic microorganisms, prokaryotic microorganisms, and viruses) as "substances," and has established a registration process for their use as microbial pesticides. EPA issues experimental use permits (EUPs) to allow persons to release these organisms into the environment on a limited basis in order to obtain information necessary to apply to have the organisms registered as microbial pesticides. EPA also allows the transfer, sale, and/or distribution of unregistered pesticides under certain circumstances in accordance with its regulations in 40 CFR 152.30. Because registered or permitted products are already subject to extensive regulation by EPA, we have entered into a memorandum of understanding with EPA stating that we consider the products to be exempt from our regulatory oversight, and paragraph (d) would largely codify the policy in this memorandum. It would also address EPA's provision for the transfer, sale, and/or distribution of unregistered pesticides under certain circumstances, and allow for the importation and interstate movement of such unregistered pesticides without APHIS' oversight, because of EPA's oversight.

Permit Requirements (§ 330.201)

Section 330.201 would describe the types of permits that APHIS issues for plant pests, biological control organisms, and associated articles, the process for applying for a permit, and the manner in which APHIS acts on permit applications.

Paragraph (a) of § 330.201 would provide information regarding the types of permits that APHIS issues for plant pests, biological control organisms, and associated articles. It would state that we issue import permits, interstate movement permits, continued curation permits, and transit permits.

Paragraph (a)(1) would provide information regarding import permits. It would state that APHIS issues import permits to persons for secure shipment from outside the United States into the territorial limits of the United States; that, when import permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States; and that, when import permits are issued to corporate persons, these persons must maintain an address or business office in the United States with a designated individual for service of process.[4]

Paragraph (a)(2) would provide information regarding interstate movement permits. It would state that interstate movement permits are issued to persons for secure shipment from any State into or through any other State; that, when interstate movement permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States; and that, when interstate movement permits are issued to corporate persons, these persons must maintain an address or business office in the United States with a designated individual for service of process.

Both import and interstate movement permits may contain conditions regarding the manner in which an organism may be moved from the destination listed on the permit. Such conditions are necessary to ensure that the organism is moved in a manner that will prevent its escape and dissemination and to ensure that the new facility to which it will be moved is capable of providing the necessary level of containment.

On a related matter, applicants for import and interstate movement permits should be aware that States and localities may have laws and regulations that restrict the movement or release of plant pests, biological control organisms, and associated articles for various reasons (for example, impact on the environment of the State or locality). We encourage applicants to consult with these authorities prior to applying for a permit.

Paragraph (a)(3) would provide information regarding continued curation permits. It would state that continued curation permits are issued in conjunction with and prior to the expiration date for an import permit or interstate movement permit, in order for the permittee to continue the actions listed on the import permit or interstate

[3] It is worth noting that, prior to the PPA, we issued permits for the movement and release of invertebrate herbivores used to control noxious weeds and microbial pathogens used to control noxious weeds pursuant to authority in the Federal Plant Pest Act (FPPA). The FPPA was superseded and repealed by the PPA.

[4] Please note that other Federal agencies have separate regulatory authority related to the importation of secure shipments of plant pests, biological control organisms, and associated articles. For example, pursuant to their general regulatory authority, DHS requires formal entry for organisms and soil that are imported via hand-carry or express courier organizations.

movement permit following the expiration of the original permit. It would also state that, when continued curation permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States. It would further state that, when continued curation permits are issued to corporate persons, these persons must maintain an address or business office in the United States with a designated individual for service of process.

Paragraph (a)(4) would provide information regarding transit permits. It would state that transit permits are issued for secure shipments through the United States, and that such permits are issued in accordance with 7 CFR part 352. As we mentioned above, § 352.5 of that part contains permitting requirements for transit permits.

However, part 352 currently provides for the transit of plant pests, but does not provide for the transit of biological control organisms. Therefore, we would amend part 352 to include references to biological control organisms. (For this reason, we would also amend part 352 to add definitions for the terms *biological control organism* and *noxious weed,* and to revise the definitions for *Deputy Administrator, person, plant pest,* and *soil.* The revised definitions would be identical to the ones we are proposing for part 330.)

Currently, part 330 contains provisions for the issuance of several additional types of permits: Permits for plant pest movement associated with national defense projects, permits for means of conveyance, and courtesy permits for organisms that are not subject to APHIS regulation. However, we no longer issue a special type of permit specifically for national defense projects; if such a permit application arises, we issue the appropriate type of movement permit, and specify as a permit condition that the use of the organism is for a national defense project. Similarly, we do not issue permits specifically for means of conveyance; if we have reason to believe the means of conveyance may be an associated article, we regulate it as such and issue the appropriate movement permit.

Until 2009, we issued courtesy permits in order to facilitate the movement of organisms that were not regulated under 7 CFR part 330, but that were similar enough to a known plant pest or biological control organism that their movement might otherwise be impeded if they were not accompanied by some sort of documentation from APHIS during transit. However, courtesy permits historically generated much confusion in the public and especially in the research community. The application form for courtesy permits was identical to the application for other types of permits, and the courtesy permit itself looked like other permits. This periodically led to the misunderstanding by some researchers that courtesy permits were required for the movement of certain organisms that were, in actuality, not subject to APHIS regulation. For these reasons, in recent years, Plant Protection and Quarantine (PPQ) has discontinued its issuance of courtesy permits for organisms that are similar to plant pests or biological control organisms, and it would not be necessary to include courtesy permits in the revised subpart.

In a related matter, § 330.207 of the current regulations states that APHIS recognizes permits issued by other Federal Agencies for the movement of regulated organisms and will issue administrative instructions or engage in correspondence with a permittee to augment the provisions of these permits through further conditions, rather than issue a duplicative permit.

We do not consider it necessary to retain those provisions in the revised subpart. First, we seldom engage in correspondence with the permittee for permits issued by another Federal agency, such as EUPs issued by EPA. Rather, if we believe that the actions authorized under the permit may place plants or plant products at risk, we discuss the matter with the issuing agency itself. Correspondingly, it is rare that we receive permit applications from applicants who have submitted a prior application to another regulatory agency. Therefore, the provisions do not reflect current Agency practices, and we believe that it is generally presupposed by the regulated community that we will recognize permits issued by other regulatory agencies for the movement of plant pests, biological control organisms, and associated articles.

Finally, we have periodically received requests from individuals to issue permits certifying organisms and associated articles that are destined for export from the United States. We note that foreign countries, rather than APHIS, set the conditions under which they will allow the importation of plant pests, biological control organisms, and associated articles from the United States. To this end, we would include a footnote stating that persons contemplating the shipment of plant pests, biological control organisms, or associated articles to places outside the United States should make arrangements directly, or through the recipient, with the country of destination for the export of the plant pests, biological control organisms, or associated articles into that country.

That being said, for certain high-risk plant pests, interstate movement permits may place conditions on the interstate movement of the organism for export purposes. This is not included in the current regulations, but reflects recent Agency policy. Such conditions are necessary to safeguard the movement of the organism to the port of export.

Paragraph (b) of § 330.201 would provide that permit applications must be submitted by the applicant in writing or electronically through one of the methods specified at *http://www.aphis.usda.gov/plant_health/permits/index.shtml,* and must be submitted in advance of the action(s) proposed on the permit application. That Web page would specify that persons may apply for a permit via the Internet through APHIS' secure site for online permit applications, and would provide a link to that portal. It would also provide that a person may submit a permit application by faxing the application to APHIS, and would specify the appropriate fax number. Additionally, it would state that an application may be obtained by calling PPQ at the number provided. Finally, it would provide that a person may submit a permit application by mailing it to APHIS at the address provided. We note that because of the need for additional administrative processing, permit applications that are submitted via fax or by mail may not be reviewed as expeditiously as those submitted through APHIS' online portal. We encourage applicants to submit their applications electronically.

Paragraph (c) of § 330.201 would provide that a permit application must be complete before we will evaluate it in order to determine whether to issue the permit requested. Guidance regarding how to complete a permit application, including guidance specific to various information blocks on the application, would be available at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.* The guidance would also specify that, in order to facilitate timely issuance of a permit, an application should be submitted at least 90 days before the actions proposed on the permit application are scheduled to take place, with additional time allotted for complex or novel applications, or applications for high-risk plant pests.

Paragraph (d) of § 330.301 would describe the actions APHIS takes on receiving a permit application. The introductory text to the paragraph

would state that APHIS reviews the information on the application to determine whether it is complete. In order to consider an application complete, APHIS may request additional information that we determine to be necessary in order to assess the risk to plants and plant products that may be posed by the actions proposed on the application. When it is determined that an application is complete, we commence review of the information provided.

Paragraph (d)(1) would describe the first part of APHIS' formal review, consultation with States, Tribes, and other individuals. We share a copy of the permit application, and the proposed permit conditions, with the appropriate State or Tribal regulatory officials, and may share them with other persons or groups to provide comment. For instance, we may share the permit application with persons or groups other than State or Tribal regulatory officials when we lack technical expertise to evaluate certain aspects of a permit application and need to solicit the opinion of individuals or groups with such expertise.

Paragraph (d)(2) would describe the second part of our review, our initial assessment of sites and facilities where the organism or article will be held or released that are listed on the permit application. Such sites and facilities may include private residences, biocontainment facilities, and field locations. Although we may not do an onsite inspection in some cases, all sites and facilities would be subject to inspection as part of the assessment. All facilities would have to be determined by APHIS to be constructed and maintained in a manner that prevents the dissemination or dispersal of plant pests, biological control organisms, or associated articles from the facility. Finally, the applicant would have to provide all information requested by APHIS regarding this assessment, and to allow all inspections requested by APHIS during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, excluding holidays). Failure to do so would constitute grounds for denial of the permit application.

Paragraphs (d)(3) and (d)(4) would describe the two possible actions we would take upon concluding review of the permit application: Issuance or denial of the requested permit. Paragraph (d)(3) would discuss permit issuance. APHIS may issue a permit to an applicant if APHIS concludes that the actions allowed under the permit would be highly unlikely to result in the introduction or dissemination of a plant pest, biological control organism, or noxious weed within the United States in a manner that presents an unacceptable risk to plants and plant products.

We would specify that the actions allowed under the permit must be highly unlikely to result in the introduction or dissemination of a plant pest, biological control organism, or noxious weed within the United States in a manner that presents an unacceptable risk to plants and plant products because we would allow the environmental release of certain plant pests and biological control organisms under the revised subpart. The considerations that lead us to determine whether to authorize the environmental release of such organisms are discussed later in this document.

Paragraphs (d)(3)(i) through (d)(3)(iv) would describe the manner in which APHIS would issue a permit under the revised subpart. Prior to issuing the permit, APHIS would notify the applicant in writing or electronically of all proposed permit conditions. The applicant would have to agree in writing or electronically that he or she, and all his or her employees, agents, and/or officers, would comply with all permit conditions and all provisions of the regulations. If the organism or associated article will be contained in a private residence, the applicant would have to state in this agreement that he or she authorizes APHIS to conduct unscheduled assessments of the residence during normal business hours if a permit is issued.

APHIS would issue the permit after it receives and reviews the applicant's agreement. The permit would be valid for no more than 3 years. During that period, the permittee would have to abide by all permitting conditions,[5] and use of the organism or article would have to conform to the intended use on the permit. Moreover, the use of organisms derived from a regulated parent organism during that period would have to conform to the intended use specified on the permit for the parent organism.

We would specify that the use of the organism or article under the permit must conform to the intended use on the permit, because, on occasion, laboratories have obtained a permit for the movement of a plant pest or biological control organism into biocontainment, and then used the organism for purposes that differed from those specified as the intended use on the permit. In such instances, APHIS was not afforded an opportunity to evaluate the uses and determine whether they present a risk to plants and plant products within the United States. There have also been instances when laboratories have claimed that subsequent generations derived from a parent organism during the time period specified on a permit are distinct organisms, and thus should not be subject to the conditions specified on the permit and may be used at the laboratory's discretion. Such unregulated use of subsequent generations or progeny could present a risk of dissemination of the pest. Hence, we would require that the use of organisms derived from a regulated parent organism must conform to the intended use specified on the permit application for the parent organism.

All activities carried out under the permit would have to cease on or before the expiration date of the permit, unless, prior to that expiration date, the permittee has submitted a new permit application and a new permit has been issued to authorize continuation of the actions.

Finally, at any point following issuance of a permit but prior to its expiration date, an inspector could conduct unscheduled assessments of the site or facility in which the organisms or associated articles are held, to determine whether they are constructed and are being maintained in a manner that prevents the dissemination of organisms or associated articles from the site or facility. As with inspections associated with our initial assessment of sites or facilities prior to permit issuance, the permittee would have to allow all such assessments that we request during normal business hours. Failure to allow such assessments would constitute grounds for revocation of the permit.

Paragraph (d)(4) would set forth the conditions under which APHIS may deny an application for a permit. Currently, in § 330.204 of the regulations, APHIS will deny a permit application when such movement would involve a danger of dissemination of the pest. Danger of plant pest dissemination may be deemed to exist when any of the following five conditions occurs:

- No acceptable safeguards adequate to prevent plant pest dissemination can be arranged.
- The destructive potential of the plant pest to plants, and parts and products thereof, should it escape despite proposed safeguards, outweighs the probable benefits to be derived from

[5] Permitting conditions may reference the regulations and policies of other Federal agencies. For example, an import permit may provide conditions that a permittee must abide by in order for customs entry of his or her shipment to occur pursuant to CBP's regulations in title 19 of the CFR.

the proposed movement and use of the pest.

- The applicant, as a previous permittee, failed to maintain the safeguards or otherwise observe the conditions prescribed in a previous permit and failed to demonstrate his ability or intent to observe them in the future.
- The movement is adverse to the conduct of an eradication, suppression, control, or regulatory program of APHIS.
- The movement is objected to in writing by an appropriate official of a State, Territory, or possession, or the District of Columbia, on the ground it will involve a danger of dissemination of the plant pest into the State, Territory or possession, or District.

Although the current regulations set out criteria that will factor into APHIS' judgment of risk and may lead us to deny a permit application, certain of the considerations have been understood by regulated entities to be absolute, and may have dissuaded persons from submitting applications for which we would have likely issued a permit. For example, for several years, there was an erroneous but widespread interpretation that the last condition afforded States and territories the right to "veto" permit applications. From this perspective, the current criteria may appear too strict.

Conversely, the current regulations do not mention circumstances that may arise during the application process that would call into question that person's ability to comply effectively with permitting conditions, such as an applicant refusing to allow APHIS to inspect a biocontainment facility listed on the application, and would thus make it unlikely that we would issue him or her a permit.

Accordingly, we are proposing to revise the conditions under which the Administrator may deny a permit application. The revised conditions would be the following:

- APHIS concludes that the actions proposed in the permit application would present an unacceptable risk to plants and plant products because of the introduction or dissemination of a plant pest, biological control organism, or noxious weed within the United States.

This condition is intended to replace the current first condition, which does not appear to allow for environmental release of a plant pest or biological control organism, and the second condition, sometimes referred to as the "balancing" condition, which can be construed to suggest that APHIS will issue a permit for a high-risk movement or use of a regulated organism, provided that the benefits potentially derived from that movement or use may be equally great or greater. However, it is APHIS policy to base its decisions regarding permit issuance for the movement or use of plant pests, biological control organisms, and associated articles solely on an assessment of potential risk to plants and plant products associated with that movement or use.

We would retain the following two conditions drawn substantially from the current regulations:

- The actions proposed in the permit application would be adverse to the conduct of an APHIS eradication, suppression, control, or regulatory program.
- A State or Tribal executive official, or a State or Tribal plant protection official authorized to do so, objects to the movement in writing and provides specific, detailed information that there is a risk the movement will result in the dissemination of a plant pest or noxious weed into the State, APHIS evaluates the information and agrees, and APHIS determines that such plant pest or noxious weed risk cannot be adequately addressed or mitigated.

We would add the following conditions:

- The applicant does not agree to observe all of the proposed permit conditions that APHIS has determined are necessary to mitigate identified risks.
- The applicant does not provide information requested by APHIS as part of an assessment of sites or facilities, or does not allow APHIS to inspect sites or facilities associated with the actions listed on the permit application.
- APHIS determines that the applicant has not followed prior permit conditions, or has not adequately demonstrated that they can meet the requirements for the current application.

This last condition is intended to clarify the current third condition, which states that a permit application may be denied if the applicant, as a previous permittee, failed to maintain the safeguards or otherwise observe the conditions prescribed in a previous permit and failed to demonstrate his ability or intent to observe them in the future. Certain applicants have sought to interpret this current condition to suggest that actions taken under a previous permit cannot, on their own, serve as a basis for denying a future permit.

This interpretation is incorrect. In deciding to issue a permit, APHIS often relies on the previous actions of an applicant to render a judgment regarding the likelihood that the applicant can comply with the permitting conditions. As a result, this last condition would also provide a list of factors that could lead us to a determination that the applicant cannot comply with the permit conditions:

- The applicant, or a partnership, firm, corporation, or other legal entity in which the applicant has a substantial interest, financial or otherwise, has not complied with any permit that was previously issued by APHIS.
- Issuing the permit would circumvent any order denying or revoking a previous permit issued by APHIS (for example, by issuing a permit to an immediate family member of a person with a lengthy record of non-compliance with previous permits issued.)
- The applicant has previously failed to comply with any APHIS regulation.
- The applicant has previously failed to comply with any other Federal, State, or local laws, regulations, or instructions pertaining to plant health.
- The applicant has previously failed to comply with the laws or regulations of a national plant protection organization or equivalent body, as these pertain to plant health.
- APHIS has determined that the applicant has made false or fraudulent statements or provided false or fraudulent records to APHIS.
- The applicant has been convicted or has pled *nolo contendere* to any crime involving fraud, bribery, extortion, or any other crime involving a lack of integrity.

Proposed paragraph (d)(5) would discuss withdrawal of a permit application. Any permit application could be withdrawn; however, applicants who wish to withdraw a permit application would have to provide this request in writing to APHIS. APHIS would provide written notification to the applicant as promptly as circumstances allow regarding reception of the request and withdrawal of the application.

Proposed paragraph (d)(6) of § 330.201 would discuss cancellation of a permit. Any permit that has been issued could be canceled at the request of the permittee. If a permittee wishes a permit to be canceled, he or she would have to provide the request in writing to APHIS–PPQ. Whenever a permit is canceled, APHIS would notify the permittee in writing regarding such cancellation.

Paragraph (d)(7) would discuss revocation of a permit. APHIS could revoke a permit for any of the following reasons:

- After issuing the permit, APHIS obtains information that would have

otherwise provided grounds for us to deny the permit application.

- APHIS determines that the actions undertaken under the permit have resulted in or are likely to result in the introduction into or dissemination within the United States of a plant pest or noxious weed in a manner that presents an unacceptable risk to plants or plant products.
- APHIS determines that the permittee, or any employee, agent, or officer of the permittee, has failed to comply with a provision of the permit or the regulations under which the permit was issued.[6]

Paragraph (d)(8) would discuss amendment of permits. Amendments could occur at the request of the permittee, or may be initiated by APHIS. If a permittee determines that circumstances have changed since the permit was initially issued and wishes the permit to be amended accordingly, he or she would have to contact APHIS to request the amendment and may have to provide supporting information justifying the amendment.

APHIS would review the request, and may amend the permit if only minor changes are necessary. Requests for more substantive changes could require a new permit application.

Prior to issuance of an amended permit, depending on the nature of the amendments, the permittee may have to agree in writing that he or she, and his or her employees, agents, and/or officers, would comply with the amended permit and conditions.

With regard to amendments initiated by APHIS, we could amend any permit and its conditions at any time, upon determining that the amendment is needed to address newly identified considerations concerning the risks presented by the organism or the activities being conducted under the permit. We would also be able to amend a permit at any time to ensure that the permit conditions are consistent with all of the requirements of the regulations; for example, if a subsequent rulemaking prohibits certain categories or types of organisms from being moved in certain means of conveyance, and the permit lacks these specific prohibitions.

As soon as circumstances allow, APHIS would notify the permittee of the amendment to the permit and the reason(s) for it. Depending on the nature of the amendment, the permittee may have to agree in writing or electronically that he or she, and his or her employees, agents, and/or officers, will comply with the permit and conditions as amended before APHIS would issue the amended permit. If APHIS requests such an agreement, and the permittee does not agree in writing that he or she, and his or her employees, agents, and/or officers, will comply with the amended permit and conditions, the existing permit would be revoked.

Paragraph (d)(9) would discuss suspension of actions authorized under a permit. It would state that we may suspend authorization of actions authorized under a permit if we identify new factors that cause us to reevaluate the risk associated with those actions. In such instances, we would notify the permittee in writing of this suspension and the reasons for it. This notification would also state the actions for which we are suspending authorization. Depending on the results of our evaluation, we would subsequently contact the permittee to remove the suspension, amend the permit, or revoke the permit.

Paragraph (d)(10) would establish procedures in the event that a person whose application has been denied, whose permit has been revoked or amended, or whose authorization for actions authorized under a permit has been suspended, wishes to appeal the decision.

Biological Control Organisms (§ 330.202)

The PPA defines a biological control organism as "any enemy, antagonist, or competitor used to control a plant pest or noxious weed."

The PPA finds that "biological control is often a desirable, low-risk means of ridding crops and other plants of plant pests, and its use should be facilitated" by APHIS and other agencies. In accordance with the PPA, APHIS authorizes the movement and environmental release of both biological control organisms through the issuance of permits.

Since the PPA was enacted, we have published several documents in the **Federal Register** that have discussed codifying our permitting processes for biological control organisms. On each occasion, individuals who support the use of biological control have requested that we consider such organisms to be distinct from plant pests, and to regulate them in a manner that facilitates, rather than restricts, their movement and environmental release. Certain of these commenters have stated that APHIS should regulate biological control organisms only when their efficacy in controlling their target plant pest or noxious weed is not adequately established.

We regulate biological control organisms pursuant to the PPA insofar as they may pose a plant pest risk. We consider it necessary to exercise a degree of regulatory oversight regarding the movement or environmental release of such biological control organisms, even when their efficacy is well established.

It is worth noting, in that regard, that biological control organisms are usually moved for eventual environmental release. This is alluded to in the PPA's definition of biological control organism, which specifies that an organism must be used, that is, actively employed to control a plant pest or noxious weed in order for it to be considered a biological control organism. Because biological control organisms are almost always intended for eventual release into the environment, it is not sufficient for us only to consider their use in controlling their target plant pest or noxious weed. We must also take into consideration the plant pest effects that the organism may pose to non-target plants or plant products.

If the organism is known to have non-target plant pest effects, it is consistent with APHIS' mission to prohibit or restrict its release. To the extent that we do not know these likely non-target plant pest effects, it is also prudent for us to place regulatory controls on its movement and release until these impacts and effects are better understood.

Paragraph (a) of proposed § 330.202 would provide, as a general condition for the importation, interstate movement, and environmental release of biological control organisms that are regulated under the proposed regulations, that no such biological control organism may be imported, moved interstate, or released into the environment unless a permit has been issued in accordance with proposed § 330.201 authorizing such importation, interstate movement, or environmental release, and the organism is moved or released in accordance with this permit and the proposed regulations.

Because applications for the movement of biological control organisms often request that we authorize the release of the organism into the environment, several regulations issued pursuant to the National Environmental Policy Act of 1969, as amended (NEPA, 42 U.S.C. 4321 *et seq.*) require certain procedural actions before APHIS may issue a permit: 40 CFR parts 1500–1508, which contains the regulations of the Council

[6] Pursuant to section 424 of the PPA, such failure, whether on the part of the permittee or on that of his or her employees, agents, or officers, may result in the assessment of civil or criminal penalties.

on Environmental Quality for implementing the procedural provisions of NEPA; 7 CFR part 1b, which contains USDA's NEPA implementing regulations; and 7 CFR part 372, which contains APHIS' implementing regulations. In accordance with these regulations under NEPA, before issuing a permit, APHIS must assess whether the actions proposed on the applications, either individually or cumulatively, are likely to have significant impacts on the human environment.

In order to make such an assessment, we often have to request additional information from applicants regarding the proposed release of the organism as part of our evaluation of the permit application. The end of paragraph (a) of § 330.202 would alert interested parties to this fact, and direct them to our portal on the Internet for further information regarding the types of information that may be requested and the manner in which this information will be evaluated.

The requirements in proposed paragraph (a) of § 330.202 would apply to the importation, interstate movement, and environmental release of most biological control organisms. However, we are aware that certain taxa of biological control organisms have become established throughout their geographical or ecological range in the continental United States, such that the additional release of pure cultures derived from field populations of a taxon of these organisms into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products. For such organisms, we do not consider there to be a sufficient basis in risk to require permits for their interstate movement or environmental release within the continental United States.

To reflect this, paragraph (b) of § 330.202 would state that APHIS has determined that certain biological control organisms have become established throughout their geographical or ecological range in the continental United States, such that the additional release of pure cultures derived from field populations of taxa of such organisms into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products within the United States. The paragraph would direct persons to APHIS' online portal for permit applications for a list of all such organisms.

Paragraph (b)(1) of § 330.202 would provide that pure cultures of organisms on that list may be imported into or moved interstate within the continental United States without further restriction under the regulations, and paragraph (b)(2) of § 330.202 would provide that pure cultures of organisms on the list may be released into the environment of the continental United States without further restriction under the regulations.

We have made a draft list of such organisms available on *Regulations.gov* as a supporting document for this proposed rule (see **ADDRESSES** at the beginning of this proposed rule) and request public comment on the list. While we will consider comments received on the draft list to be distinct from those received on the proposed rule, the comments received on the draft list will inform our evaluation of the suitability of the exemptions from permitting requirements contained in proposed paragraph (b) of § 330.202.

Proposed paragraph (c) of § 330.202 would establish a petition-based process by which biological control organisms would be added to the list of organisms granted exceptions from permitting requirements for their importation or interstate movement. Any person would be able to request that APHIS add a biological control organism to the list referred to in paragraph (b) of § 330.202 by submitting a petition to APHIS. We would specify that individuals should submit the petition via email to *Pests.permits@aphis.usda.gov,* or through any other means listed on APHIS' Web site at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.*

The petition would have to include the following information:

- Evidence indicating that the organism is indigenous to the continental United States throughout its geographical or ecological range, or evidence indicating that the organism has produced self-replicating populations within the continental United States for an amount of time sufficient, based on the organism's taxon, to consider that taxon established throughout its geographical or ecological range in the continental United States.
- Results from a field study where data was collected from representative habitats occupied by the biological control organism. Studies would have to include sampling for any direct or indirect impacts on target and non-target hosts of the biological control organism in these habitats. Supporting scientific literature would have to be cited.
- Any other data, including published scientific reports, that suggest that that subsequent releases of the organism into the environment of the continental United States would present no additional plant pest risk (direct or indirect) to plants or plant products.

APHIS would review the petition to determine whether it is complete. If the petition is complete, we would conduct an evaluation of the petition to determine whether there is sufficient evidence that the organism exists throughout its geographical or ecological range in the continental United States and that subsequent releases of pure cultures of field populations the organism into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products.

If we determine that there is sufficient evidence that that the organism exists throughout its geographical or ecological range in the continental United States and that subsequent releases of pure cultures of the organism into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products, we would publish a notice in the **Federal Register** announcing the availability of the petition and requesting public comment on that document.

If no comments are received on the notice, or if the comments received do not lead us to reconsider our determination, we would publish a subsequent notice in the **Federal Register** describing the comments received and stating that the organism has been added to the list referred to in proposed paragraph (b) of § 330.202.

If the comments received lead us to reconsider our determination, we would publish a subsequent notice in the **Federal Register** describing the comments received and stating our reasons for determining not to add the organism to the list referred to in proposed paragraph (b).

Proposed paragraph (e) of § 330.202 would provide that any biological control organism may be removed from the list referred to in paragraph (b) of the section if information emerges that would have otherwise led us to deny the petition to add the organism to the list. Whenever an organism is removed from the list, APHIS would publish a notice in the **Federal Register** announcing that action and the basis for it.

Soil (§ 330.203)

The regulations governing the importation, interstate movement, and transit of soil and certain stone and quarry products under permit are currently found in "Subpart—Movement of Soil, Stone, and Quarry

Products,'' §§ 330.300 through 330.302. We are proposing to remove and reserve that subpart and integrate the regulations for soil into the revised ''Subpart—Plant Pests, Biological Control Organisms, Soil, and Associated Articles'' as § 330.203. We are proposing to do so primarily in order to clarify that we regulate soil insofar as it is or may be an associated article. That is, we regulate soil insofar as it may harbor plant pests or noxious weeds: When a permit application for soil is submitted to APHIS, a soil specialist evaluates this likelihood of contamination with plant pests or noxious weeds and determines whether a permit should be issued.

As part of our revision to the soil regulations, we would also update the regulations in light of the current scientific understanding of soil and the spread of soil-borne pathogens within Canada.

Proposed paragraph (a) of § 330.203 would state that the Administrator has determined that, unless it has been sterilized, soil is an associated article, and is thus subject to the permitting requirements of § 330.201. It would also provide two conditions under which the movement of soil would not be subject to the permitting requirements of § 330.201: If the movement is regulated pursuant to other APHIS regulations in 7 CFR chapter III (*e.g.*, § 301.86–5 requires certificates for the interstate movement of soil from an area quarantined for pale cyst nematode), or if § 330.203 states that the movement does not require such a permit. This second condition would apply to the importation of most soil from Canada, and most interstate movement of soil.

Proposed paragraphs (b)(1) through (b)(3) of § 330.203 would provide conditions governing the importation of soil. First, in a similar manner to our conditions for the importation of most biological control organisms, we would require an import permit to be issued in accordance with § 330.201 for the importation of soil, and the soil to be imported under the conditions specified on the permit. We are requiring a permit so that we can evaluate the risks associated with any particular importation of soil and assign the appropriate mitigation measures.

Currently, soil may be imported from Canada without a permit, unless the soil is from Newfoundland or the Land District of Central Saanich on Vancouver Island in the Province of British Columbia; these two areas are known to be infested with pale cyst nematodes (PCN). We are proposing to amend the regulations so that soil from any area of Canada regulated by the Canadian Food Inspection Agency (CFIA), the national plant protection organization of Canada, for a soil-borne plant pest would require a permit. We are doing this because there have been recent detections of soil-borne plant pests of quarantine significance in Canada (such as PCN in Quebec and potato wart disease on Prince Edward's Island) that are not reflected in the current regulations.

We would also clarify that the proposed regulations do not pertain to soil used as a growing medium for plants for planting from Canada. Plants for planting that are intended to be imported into the United States and their growing media are regulated under 7 CFR part 319, ''Subpart—Plants for Planting.''

Plants for planting that can be inspected, treated, or handled to prevent them from spreading plant pests are designated in that subpart as restricted articles. Section 319.37–4 requires all restricted articles imported into the United States to be accompanied by a phytosanitary certificate of inspection, unless the section explicitly exempts the articles from this requirement. Paragraph (a)(1) of § 319.37–4 exempts greenhouse-grown plants from Canada imported in accordance with the provisions of a certification program administered by CFIA from this requirement; paragraph (c) of that section contains the provisions of CFIA's program.

Section 319.37–8 addresses the growing media in which a restricted article may be imported. Currently, paragraph (a) of the section prohibits the use of soil as a growing medium for plants for planting from all countries other than Canada. Paragraph (b) allows a restricted article from Canada to be imported in any medium, with the restriction that articles from Newfoundland or a certain portion of the Municipality of Central Saanich in the Province of British Columbia must be accompanied by a phytosanitary certificate containing an additional declaration that the plants were grown in a manner to prevent infestation with potato cyst nematode. We are proposing to revise paragraph (b) of § 319.37–8 so that articles from any area of Canada that is regulated by CFIA for a soil-borne plant pest would have to be accompanied by a phytosanitary certificate with an additional declaration that the plants were grown in a manner to prevent infestation with that soil-borne plant pest.

Proposed paragraphs (b)(2) through (b)(4) of § 330.203 would set forth additional conditions for certain types of importations of soil. Paragraph (b)(2) would provide additional conditions for the importation of soil via hand-carry. In addition to the requirements of proposed paragraph (b)(1), we would allow soil to be hand-carried into the United States only if the importation meets the conditions of § 330.205. That section, which is discussed later in this document, would contain our regulations governing the hand-carry of plant pests, biological control organisms, and soil.

Proposed paragraph (b)(3) would provide additional conditions for the importation of soil intended for the extraction of plant pests. Since this soil is imported precisely because it is known to contain plant pests, with very few exceptions, it is not rerouted for sterilization upon arrival in the United States. Therefore, to mitigate the risk that such soil could present a pathway for the introduction or dissemination of plant pests within the United States, we would require all such soil to be imported directly to an approved biocontainment facility.

On occasion, soil that presents a risk of harboring plant pests is imported into the United States for disposal; for example, this sometimes occurs when a natural disaster strikes an area quarantined for a soil-borne pathogen and emergency management personnel need to dispose of the resulting debris. Proposed paragraph (b)(4) would contain additional conditions for the importation of such soil. In addition to general conditions for the importation of soil, soil infested with plant pests and intended for disposal would have to be imported directly to an APHIS-approved disposal facility. Although all such facilities are subject to evaluation and approval by EPA, we would require independent APHIS approval of the facility because certain of these EPA-approved facilities are municipal landfills that may not provide adequate safeguards against plant pest dissemination.

Currently, § 330.301 restricts the importation into the United States of stone and quarry products from areas in Canada that are infested with gypsy moth. This section has at times led to confusion regarding the relationship between soil and stone and quarry products, as well as questions regarding the regulated status of articles, such as clay, that are similar to but fundamentally distinct from soil.

Proposed paragraph (b)(5) of § 330.203 would list certain articles that are not soil, and that, because of their composition or origin, present a negligible risk of serving as a medium for plant pests or noxious weeds, provided that they are free of organic material. The articles could be imported

into the United States without an import permit, unless the Administrator has issued an order stating that a particular article is an associated article. (Such orders would be maintained on PPQ's Web site, at *http://www.aphis.usda.gov/plant_health/permits/organism/soil/index.shtml*.) However, all such articles would be subject to inspection at the port of first arrival, subsequent reinspection at other locations, and other remedial measures deemed necessary by an inspector to remove any risk the items pose of disseminating plant pests or noxious weeds, and any other restrictions or prohibitions in 7 CFR chapter III. The articles would be:

- Consolidated material derived from any strata or substrata of the earth. Examples include clay (laterites, bentonite, china clay, attapulgite, tierrafino), talc, chalk, slate, iron ore, and gravel.
- Sediment, mud, or rock from saltwater bodies of water.
- Cosmetic mud and other commercial mud products.
- Stones, rocks, and quarry products.

These provisions do not mean that we would no longer restrict the movement of stone and quarry products from areas in Canada that are infested with gypsy moth. Instead, we would amend "Subpart—Gypsy Moth Host Material from Canada," § 319.77–1 through § 319.77–5, to incorporate those restrictions. Section 319.77–2 of that subpart contains a list of articles designated regulated articles; we would amend that section by adding a new paragraph (i) that would designate stone and quarry products as regulated articles. Section 319.77–4 contains conditions for the importation of regulated articles; we would amend the section by adding a new paragraph (d) that would provide that stone and quarry products originating in a Canadian area known to be infested with gypsy moth may be imported into the United States only if they are destined for an infested area of the United States and will not be moved through any noninfested areas of the United States, and may be moved through the United States if they are moved only through infested areas. We consider this subpart a more appropriate location for the restrictions.

Proposed paragraph (c) of § 330.203 would provide general conditions governing the interstate movement of soil. Most soil could be moved interstate without prior issuance of an interstate movement permit in accordance with § 330.201, or further restriction under the regulations. However, all soil moved interstate within the United States would still be subject to any movement restrictions and remedial measures specified for such movement in 7 CFR part 301.

As we mentioned earlier in this document, part 301 contains our regulations that designate certain areas of the United States as quarantined areas for a particular plant pest, and that prohibit or restrict the movement in interstate commerce of certain host articles of that pest. The provisions currently in our regulations in § 330.302 mention certain sections of part 301 in which soil is considered a regulated article, such as our Japanese beetle and gypsy moth regulations, but omit others, such as our golden nematode and PCN regulations, and do not take into consideration the possibility that outbreaks of new plant pests within the United States may lead us to regulate the interstate movement of soil from areas quarantined for those or other pests.

Proposed paragraph (c)(2) would provide conditions for the interstate movement within the continental United States of soil intended for the extraction of plant pests. Again, since such soil is moved precisely because it is known to contain plant pests, it is, by definition, an associated article, and therefore would require an interstate movement permit issued in accordance with § 330.201 in order to be moved. Moreover, because of the intended use of the soil, in order to mitigate the risk of the dissemination of plant pests, the soil would have to be moved directly to an approved biocontainment facility, and in a secure manner that prevents its dissemination into the outside environment.

Proposed paragraph (c)(3) would contain additional conditions for the interstate movement within the continental United States of soil infested with plant pests and intended for disposal. We would require issuance of an interstate movement permit prior to movement, and would require that all such soil to be moved directly to an APHIS-approved disposal facility, and in a secure manner that prevents its dissemination into the outside environment.

Proposed paragraph (c)(4) would contain additional conditions for the interstate movement of soil samples from an area quarantined in accordance with 7 CFR part 301 for chemical or compositional testing or analysis. Such soil could be moved without prior issuance of an interstate movement permit in accordance with § 330.201 or further restriction under 7 CFR chapter III, provided that the soil is moved to a laboratory that has entered into and is operating under a compliance agreement with APHIS, is abiding by all terms and conditions of the compliance agreement, and is approved by APHIS to test and/or analyze such samples.

Proposed paragraph (c)(5) would contain additional conditions for the interstate movement of soil to, from, or between Hawaii, the territories, and the continental United States. In addition to all general conditions for interstate movement of soil, soil could be moved interstate to, from, or between Hawaii, the territories, and the continental United States only if an interstate movement permit has been issued for its movement in accordance with § 330.201. This condition would apply to all soil moved to, from, or between Hawaii, the territories, and the continental United States. In addition to this provision, soil moved to, from, or between Hawaii, the territories, and the continental United States with the intent of extracting plant pests would still be subject to the conditions of proposed paragraph (c)(2) of the section, and would therefore have to be moved directly to an approved biocontainment facility. Similarly, soil infested with plant pests and intended for disposal would be subject to the conditions of proposed paragraph (c)(3) of the section, and would therefore have to be moved directly to an APHIS-approved disposal facility.

Proposed paragraph (d) would contain conditions regarding the transit of soil. Such movement would require a transit permit issued in accordance with 7 CFR part 352.

The regulations in § 330.300 currently exempt movements of soil governed by § 318.60 or § 319.69 from permitting requirements. Section 318.60 currently prohibits the movement of sand (other than clean ocean sand), soil, or earth around the roots of plants from Hawaii, Puerto Rico, or the Virgin Islands into or through any other State, Territory, or District of the United States, unless the movement is in either direction between Puerto Rico and the Virgin Islands, or the soil is intended for experimental or scientific use by USDA. We would amend § 318.60 to clarify that it pertains only to the movement of soil around the roots of plants, and that all other movement of soil from Hawaii, Puerto Rico, or the Virgin Islands, other than that soil around the roots of plants, is regulated under 7 CFR part 330. We consider this amendment necessary primarily so that we would not regulate the movement of such soil in two different subparts, and secondarily so that the section may not be used to circumvent the regulations in part 330.

"Subpart—Packing Materials," § 319.69 through § 319.69–5, contains

our regulations regarding plants and plant products used as packing materials for imported commodities. Section 319.69 prohibits the use of soil containing an appreciable mixture of vegetable matter from being used as packing material, except for soil authorized as safe for packing by other rules and regulations in the subpart. Section 319.69–1 specifies that soil containing an appreciable admixture of vegetable matter is covered by this prohibition because its decaying vegetation or plant remains carries a definite pest risk. Finally, § 319.69–5 states that the following soil may be used as packing material: Peat, peat moss, or osmunda fiber.

After reviewing this section in light of the current scientific understanding of soil, as reflected in our proposed revision to the definition of *soil* in § 330.100, we have determined that this section does not refer to soil, as it is currently understood, but to the organic decaying vegetative matter for which soil may serve as a medium, and of which peat, peat moss, and osmunda fiber are all examples. We have also determined that an instance may arise when the mitigation measures that we require in part 319 for the importation of a plant, plant part, or plant product may also address the risk associated with using organic decaying vegetative matter as a packing material for that commodity.

Therefore, we would amend the existing prohibition in § 319.69 on the use of soil as a packing material so that it instead prohibits the use of organic decaying vegetative matter as a packing material. We would remove § 319.69–1(b), which considers matter containing decaying vegetation or plant remains to be soil. We would establish an exemption for any organic decaying vegetative matter expressly authorized to be used as a packing material elsewhere in part 319. Finally, we would revise the heading of § 319.69–5 to make it clear that it does not pertain to the use of soil as a packing material, but organic decaying vegetative matter.

Exceptions to Permitting Requirements for the Importation or Interstate Movement of Certain Plant Pests (§ 330.204)

Section 7711 of the PPA provides that the Secretary of Agriculture may issue regulations to allow the importation and the movement in interstate commerce of plant pests without further restriction, if the Secretary finds that a permit for such movement is not necessary. The section further states that if the Secretary does issue such regulations, any person may petition him or her to add a plant pest or remove a plant pest from this list of pests. Finally, the section provides that if a petition is submitted, the Secretary will act on the petition and notify the petitioner of the action he or she will take on the petition.

Section 330.204 would establish such regulations and petition process. The introductory paragraph would state that, pursuant to section 7711 of the PPA, the Administrator has determined that certain plant pests may be imported into or may move in interstate commerce within the continental United States without restriction. The list of all such plant pests would be on the PPQ Web site.

Paragraph (a) of the section would describe the three categories of plant pests that comprise the list. In order to be included on the list, a plant pest would have to:

- Be from field populations or lab cultures derived from field populations of a taxon that is established throughout its entire geographical or ecological range within the continental United States; or
- Be sufficiently attenuated so that it no longer poses a risk to plants or plant products; or
- Be commercially available and raised under the regulatory purview of other Federal agencies.

In our 2001 proposed rule, paragraph (c) of § 330.202 would have established a "no permit necessary" list for certain indigenous plant pest species that were already distributed throughout the continental United States and are known to commonly accompany plants or plant products moved in commerce. The first category aligns with the criterion for that 2001 list. We would not require permits for plant pests from a field population or lab culture derived from a field population of a taxon that is established throughout its entire geographical or ecological range within the United States because such pests are ubiquitous within the continental United States.

The second category reflects the fact that *in vitro* attenuation of plant pests such as phytopathogenic fungi, while rare, does occur. When a pest becomes attenuated, there is no longer a sufficient basis for us to presume that the pest presents a risk of directly or indirectly injuring, causing damage to, or causing disease in plants or plant products; in other words, an attenuated pest *de facto* no longer falls within the scope of the definition of *plant pest* under the PPA.

(In order to avoid confusion and the possible unregulated movement of the virulent strains of the plant pest, the list would specify the strains of the plant pest that APHIS considers attenuated of their pathogenicity.)

The third category of plant pests is intended to avoid duplicative or conflicting regulatory oversight of certain plant pests. For example, although it is a plant pest, *Penicillium chrysogenum* is regulated by the Food and Drug Administration (FDA).

We have made a draft list of plant pests that may be imported or move in interstate commerce within the continental United States without restriction available on *Regulations.gov* as a supporting document for this proposed rule, and request public comment regarding that list. The list largely mirrors the list contained in the 2001 proposed rule, but also contains certain plant pests that belong to the second and third categories.

Paragraph (b) of § 330.204 would contain a petition process to add a plant pest to the list. Any person would be able to petition to have an additional plant pest added to the list. To submit a petition, the person would have to provide, in writing, information supporting the placement of a particular pest in one of the categories listed in paragraph (a) of § 330.204.

Information that the plant pest belongs to a taxon that is established throughout its entire geographical or ecological range within the United States would have to include scientific literature, unpublished studies, or data regarding:

- The biology of the plant pest, including characteristics that allow it to be identified, known hosts, and virulence;
- The geographical or ecological range of the plant pest within the continental United States; and
- The areas of the continental United States within which the plant pest is established.

The first category of information is intended to provide us with basic information regarding the plant pest for which unrestricted movement is sought. The second and third categories would aid our determination regarding whether the plant pest is established throughout its ecological or geographical range within the continental United States.

Information that the plant pest has been attenuated of its pathogenicity would have to include experimental data, published references, or scientific information regarding such attenuation.

Information that the plant pest is commercially available and raised under the regulatory purview of another Federal agency would have to include a citation to the relevant law, regulation,

or order under which the agency exercises such oversight. For example, *Penicillium chrysogenum* is regulated by FDA under the Kefauver-Harris drug amendments of 1962.

APHIS would review the information contained in the petition to determine whether it is complete. In order to consider the petition complete, APHIS may require additional information to determine whether the plant pest belongs to one of the categories listed in paragraph (a) of § 330.204. When it is determined that the information is complete, we would commence review of the petition.

If, after review of the petition, we determine that there is insufficient evidence that the plant pest belongs to one of the three categories listed in paragraph (a) of § 330.204—for example, the plant pest is known to exist throughout its entire geographical range in the continental United States, but population densities in certain areas are not sufficient to consider it established throughout its range—we would deny the petition, and notify the petitioner in writing regarding this denial.

Conversely, if, after review of the petition, we determine that the plant pest belongs to one of the categories in paragraph (a), we would publish a notice in the **Federal Register** that announces the availability of the petition and any supporting documentation to the public, that states that we intend to add the plant pest to the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction, and that requests public comment.

If no comments are received on the notice, or if, based on the comments received, we determine that our conclusions regarding the petition have not been affected, we will publish in the **Federal Register** a subsequent notice stating that the plant pest has been added to the list.

Under paragraph (c) of § 330.204, any person could submit, in writing, a petition to have a plant pest removed from the list. The petition would have to contain independently verifiable information demonstrating that our initial determination that the plant pest belongs to one of the categories in paragraph (a) of the section should be changed, or that additional information is now available that would have caused us to change the initial decision.

APHIS would review the information contained in the petition to determine whether it is complete. In order to consider the petition complete, we may require additional information supporting the petitioner's claim. When it is determined that the information is complete, we would commence review of the petition.

If, after review of the petition, we determine that there is insufficient evidence to suggest that our initial determination should be changed, we would deny the petition, and notify the petitioner in writing regarding this denial.

If, after review of the petition, we determine that there is a sufficient basis to suggest that our initial determination should be changed, we would publish a notice in the **Federal Register** that announces the availability of the petition, and that requests public comment regarding removing the plant pest from the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction.

If no comments are received on the notice, or if the comments received do not affect our conclusions regarding the petition, we would publish in the **Federal Register** a subsequent notice stating that the plant pest has been removed from the list.

Paragraph (d) of § 330.204 would provide for APHIS-initiated changes to the list. It would provide that APHIS may propose to add a plant pest to or remove a pest from the list without a petition, if we determine that there is sufficient evidence that the plant pest belongs to one of the categories listed in paragraph (a) of the section, or if evidence emerges that leads us to reconsider our initial determination that the plant pest was or was not in one of the categories listed in paragraph (a) of the section. We would publish a notice in the **Federal Register** announcing this proposed addition or removal, making available any supporting documentation that we prepare, and requesting public comment.

If no comments are received on the notice, or if the comments received do not affect our conclusions, we will publish a subsequent notice in the **Federal Register** stating that the plant pest has been added to or removed from the list.

Hand-Carry of Plant Pests, Biological Control Organisms, and Soil (§ 330.205)

Currently, we authorize the importation of plant pests in personal baggage (referred to as "hand-carry") under § 330.212 of the regulations. The regulations provide that the person importing the plant pest must show the permit authorizing the importation to an inspector at the port of arrival where the baggage will be inspected, that the conditions specified on the permit must be observed, that an inspector will oversee the movement of the plant pest, that the owner of the plant pest will be responsible for all costs incidental to forwarding the plant pest prior to clearance, and that an inspector may specify and supervise the application of safeguards to prevent the dissemination of the pest until it is forwarded.

The 2003 OIG audit referenced at the beginning of this document pointed out that the hand-carry process in place at the time did not provide guidance regarding what materials may be hand-carried or who may hand-carry, and that APHIS did not track hand-carried materials to ensure that they arrive at the point of destination listed on the permit. For these reasons, the audit strongly suggested that we issue regulations to prohibit hand-carry of regulated organisms into the United States, and to explicitly state that all organisms must be imported into the United States via a bonded commercial carrier.

However, certain plant pests and biological control organisms are highly perishable, and may remain viable only if they are imported into the United States directly and without rerouting. We have also found that it is often useful, from a safeguarding perspective, to authorize hand-carry in order to have an expert regarding the organism or article exercise direct and continuous oversight of its importation.

Therefore, we would include provisions for hand-carry in this proposed rule. These provisions, which would be contained in § 330.205, would reflect current Agency processes regarding hand-carry.

The introductory text of § 330.205 would state that plant pests, biological control organisms, and soil may be hand-carried into the United States only in accordance with the provisions of the section.

Proposed paragraph (a) of § 330.205 would discuss the first such provision, authorization to hand-carry. In order to obtain such authorization, a person would have to apply for an import permit for the plant pest, biological control organism, or soil, in accordance with § 330.201, and specify hand-carry of the organism or article as the method of proposed movement.

The application would also have to specify the individual or individuals who would hand-carry the plant pest, biological control organism, or soil into the United States. If we authorize this individual or these individuals to hand-carry, this authorization could not be transferred to, nor actions under it performed by, individuals other than those identified on the permit application.

Under proposed paragraph (b) of § 330.205, the permittee would have to notify APHIS through our online portal for permit applications or by fax after the permittee has obtained an import permit but no less than 20 days prior to movement and provide the following information in order to receive a hand-carry authorization:

- A copy of the face page of the passport for the individual or individuals who will hand-carry the plant pest, biological control organism, or soil.
- A description of the means of conveyance in which the individual or individuals will travel, including flight number and airline name for air travel, or vehicle license number or other identifying number for other modes of transportation.
- Expected date and time of first arrival.
- Expected port of first arrival.
- Travel itinerary from port of first arrival to final destination.

We would require authorized identification, the description of the means of conveyance, and the expected date, time, and port of first arrival because, pursuant to the regulations in § 330.105, hand-carried organisms or soil, like all other imported articles, must be presented for inspection at the port of first arrival, and this information would help us ensure that the inspection takes place as expeditiously as possible. We would require the travel itinerary from the port of first arrival to the final destination in order to ensure that the individual does not intend to make prolonged stops en route that could result in breach of safeguarding and increase the risk of accidental dissemination of the organism or soil. The information also would help us respond promptly to accidental dissemination of the organism or soil en route to the final destination.

Under proposed paragraph (c) of § 330.205, the permittee or his or her designee would have to notify APHIS within 24 hours of arrival of the hand-carried plant pest, biological control organism, or soil at the biocontainment facility or other authorized point of destination. This notification would have to state that the plant pest, biological control organism, or soil has arrived at its destination and that the package in which it was hand-carried has remained sealed until arrival. Notification could be by fax or email, or via APHIS' permitting Web site.

Proposed paragraph (d) of § 330.205 would discuss denial, amendment, or cancellation of authorization to hand-carry. It would state that APHIS may deny a request to hand-carry, or amend or cancel any hand-carry authorization at any time, if we deem such action necessary to prevent the introduction or dissemination of plant pests or noxious weeds within the United States.

In a similar manner, proposed paragraph (e) of § 330.205 would state that any person whose request to hand-carry has been denied, or whose hand-carry authorization has been amended or canceled, would be able to appeal the decision in writing to APHIS.

Packaging Requirements (§ 330.206)

We are proposing to revise the packaging requirements for the movement of plant pests, currently found in § 330.210. The revised requirements would be contained in proposed § 330.206.

The introductory text of the section would state that shipments in which plant pests, biological control organisms, and associated articles are imported into, moved interstate, or transited through the United States must meet the general packaging requirements of the section, as well as all specific packaging requirements on the permit itself.

Proposed paragraph (a) would contain general packaging requirements. All shipments would have to consist of an outer shipping container and at least two packages within the container. Both the container and the inner packages would have to be securely sealed to prevent the dissemination of the enclosed plant pests, biological control organisms, or associated articles.

Paragraph (a)(1) would contain general requirements for the outer shipping container. The outer shipping container would have to be rigid, impenetrable, and durable enough to remain sealed and structurally intact in the event of dropping, lateral impact with other objects, and other shocks incidental to handling.

Paragraph (a)(2) would contain requirements for inner packages. The innermost package or packages within the shipping container would have to contain all of the organisms or articles that will be moved. As a safeguard, the innermost package would have to be placed within another, larger package, for example, bagged and sealed petri samples placed within a sealed cooler. All packages within the shipping container would have to be constructed or safeguarded so that they will remain sealed and structurally intact throughout transit. The packages would also have to be able to withstand changes in pressure, temperature, and other climatic conditions incidental to shipment.

Paragraph (b) would contain general requirements for packing material. It would specify that packing material must be free of plant pests, noxious weeds, or associated articles, and must be new, or must have been sterilized or disinfected prior to reuse. Packing material would also have to be suited for the enclosed organism or article, as well as any medium in which the organism or article will be maintained, and should not be capable of harboring or being a means of the dissemination of the organism or article.

We would provide guidance regarding suitable outer shipping containers, inner packages, and packaging on the PPQ Web site.

Paragraph (c) would provide that packing materials, including media and substrates, would have to be destroyed by incineration, be decontaminated using autoclaving or another approved method, or otherwise be disposed of in a manner specified in the permit itself. It would also provide that shipping containers could not be reused, except those that have been sterilized or disinfected prior to reuse.

Proposed paragraph (d) would state that permittees who fail to meet the requirements of the section may be held responsible for all costs incident to inspection, rerouting, repackaging, subsequent movement, and any treatments.

Cost and Charges (§ 330.207)

Proposed § 330.207 would state that the inspection services of APHIS inspectors during regularly assigned hours of duty and at the usual places of duty would be furnished without cost. It would also state that APHIS would not be responsible for any costs or charges incidental to inspections or compliance with the provisions of this subpart, other than for the inspection services of the inspector.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This proposed rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order

13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides an initial regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the *Regulations.gov* Web site (see **ADDRESSES** above for instructions for accessing *Regulations.gov*).

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. However, we do not currently have all of the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

APHIS is proposing to revise its regulations regarding the importation, interstate movement, and environmental release of plant pests to incorporate provisions regarding biological control organisms (BCOs) and the movement of soils from which plant pests and BCOs are extracted. The proposed rule would revise and add definitions, streamline the permitting and compliance processes, and provide APHIS with increased flexibility in the regulation of plant pests. Parts 318, 319, and 352 of 7 CFR chapter III would also be updated to reflect the proposed changes in part 330.

A principal consequence of the proposed rule would be a streamlining of our permitting process and possible reduction in the number of permits issued under part 330, which numbered 6,538 in 2015. Approximately 33 percent of these permits (2,158) authorized the movement or environmental release of a plant pest or BCO that APHIS is proposing to exempt from permitting. While we do not expect the proposed rule would result in one-third fewer permits as one permit may list multiple BCOs or plant pests, we can say with confidence that the permitting burden would be reduced for applicants and that the permitting process could be expedited. We expect that affected entities would benefit from a 10 to 30 percent reduction in the overall time spent applying for and receiving permits under part 330. Assuming the time required to submit an application is 1 hour and assuming an average hourly wage of $45.50 per hour, then for the 6,538 permits issued in 2015, the time savings expected under the proposed rule would have totaled between 654 and 1,961 hours, which equates to a cost savings of between about $29,748 and $89,244.

The proposed rule would codify existing practices by allowing entities requesting permits to apply electronically rather than by using the mail only. Expanded use of online permit applications through APHIS' portal would result in time and cost savings as compared to applying by mail using paper applications.

Listing of exempted organisms on an APHIS–PPQ Web site, transparent procedures for petitioning for exceptions or exemptions to permitting, and provision for a notice-based process for adding and removing listed organisms would also combine to make an efficient, transparent, and user-responsive system that would facilitate the movement and environmental release of plant pests and BCOs.

Regulated entities would continue to incur time costs associated with providing information during the permitting application process, and with meeting somewhat more robust recordkeeping (maintaining records) requirements in certain instances such as with soil imports and risk based permits. The time required overall for permitting would be reduced, however, because of the newly excepted organisms.

The proposed revisions to 7 CFR part 330 would benefit entities, large and small, by increasing the efficiency of the permitting and compliance processes for plant pests, BCOs, and soils from which plant pests and BCOs are extracted, and by improving the general clarity and transparency of these regulations. The proposed rule also would facilitate the Agency's coordination with other Federal and State agencies in regulating the movement and environmental release of plant pests and BCOs. The majority of entities that would benefit from this rule are small entities, based on information obtained from the Economic Census.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the processes established by this proposed rule, we have prepared a draft environmental impact statement (EIS). The EIS was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The draft EIS is available on *Regulations.gov* for review and comment, and may be accessed via the Internet address provided above under the heading **ADDRESSES**. Copies may also be obtained by contacting the individual listed below the section titled **FOR FURTHER INFORMATION CONTACT**.

A notice of availability regarding the draft EIS will also be published by the Environmental Protection Agency in the **Federal Register**.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), some of the reporting, recordkeeping, and third party disclosure requirements included in this proposed rule are in the process of being reinstated under Office of Management and Budget (OMB) control number 0579–0054. The new reporting requirements included in this proposed rule have been submitted as a new information collection for approval to OMB.

Please send comments on the information collection request to OMB's Office of Information and Regulatory Affairs via email to *oira_submission@omb.eop.gov*, Attention: Desk Officer for APHIS. Please state that your comments refer to Docket No. APHIS–2008–0076. Please send a copy of your comments to USDA, using one of the methods described under **ADDRESSES** at the beginning of this document.

Under the PPA, the Secretary of Agriculture has authority to carry out operations or measures to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests. Section 7711(a) of the Act provides that "no person shall import, enter, export, or move in interstate commerce any plant pest, unless the importation, entry, exportation, or movement is authorized under general or specific permit and in accordance with such regulations as the Secretary may issue to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States." The Act gives USDA the flexibility to respond appropriately to a wide range of needs and circumstances to protect American agriculture against plant pests.

In addition, section 412(a) of the Act provides that the Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of, among other things, any biological control organism if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States. The Act defines a biological control organism as ''any enemy, antagonist, or competitor used to control a plant pest or noxious weed.''

APHIS regulations implementing these aspects of the Plant Protection Act are contained (in part) in 7 CFR part 330.

APHIS is proposing to revise: (1) Regulations regarding the movement of plant pests; (2) criteria regarding the movement and environmental release of biological control organisms, and proposing to establish regulations to allow the importation and movement in interstate commerce of certain types of plant pests without restriction by granting exceptions from permitting requirements for those pests; and (3) regulations regarding the movement of soil. This proposal would clarify the factors that would be considered when assessing the risks associated with the movement of certain organisms and facilitate the movement of regulated organisms and articles in a manner that also protects U.S. agriculture.

This proposed rule replaces a previously published proposed rule, which APHIS is withdrawing as part of this document. This proposal would clarify the factors that would be considered when assessing the risks associated with the movement of certain organisms and facilitate the movement of regulated organisms and articles in a manner that also protects U.S. agriculture.

Implementing this rule will require respondents to complete a new petition process to remove permitting requirements for the interstate movement of certain plant pests or biological control organisms.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 160 hours per response.

Respondents: Importers and distributors of plants and plant products; importers, brokers, distributors, retailers, and exhibitors of biological control organisms and associated articles; and operators of biocontainment facilities.

Estimated Annual Number of Respondents: 6.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Annual Number of Responses: 6.

Estimated Total Annual Burden on Respondents: 960 hours (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

A copy of the information collection may be viewed on the *Regulations.gov* Web site or in our reading room. (A link to *Regulations.gov* and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) Copies can also be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483. APHIS will respond to any information collection request-related comments in the final rule. All comments will also become a matter of public record.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

Lists of Subjects

7 CFR Part 318

Cotton, Cottonseeds, Fruits, Guam, Hawaii, Plant diseases and pests, Puerto Rico, Quarantine, Transportation, Vegetables, Virgin Islands.

7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

7 CFR Part 330

Customs duties and inspection, Imports, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

7 CFR Part 352

Customs duties and inspection, Imports, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we propose to amend 7 CFR parts 318, 319, 330, and 352 as follows:

PART 318—STATE OF HAWAII AND TERRITORIES QUARANTINE NOTICES

■ 1. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

§ 318.60 [Amended]

■ 2. In § 318.60, paragraph (c) is amended by adding the words ": *And provided finally,* that the prohibitions in this paragraph do not apply to the movement of soil from Hawaii, Puerto Rico, and the Virgin Islands, other than that soil around the roots of plants; movement of soil that is not around the roots of plants is regulated under part 330 of this chapter'' after the words ''paragraphs (c)(1), (2), and (3) of this section''.

PART 319—FOREIGN QUARANTINE NOTICES

■ 3. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

■ 4. In § 319.37–8, paragraph (b)(2) is revised to read as follows:

§ 319.37–8 Growing media.

* * * * *

(b) * * *

(2) A restricted article from an area of Canada regulated by the national plant

protection organization of Canada for a soil-borne plant pest may only be imported in an approved growing medium if the phytosanitary certificate accompanying it contains an additional declaration that the plant was grown in a manner to prevent infestation by that soil-borne plant pest.

* * * * *

■ 5. Section 319.69 is amended as follows:

■ a. By revising paragraph (a)(8); and

■ b. By removing paragraph (b)(4).

The revision to read as follows:

§ 319.69 Notice of quarantine.

(a) * * *

(8) Organic decaying vegetative matter from all countries, unless the matter is expressly authorized to be used as a packing material in this part. Exceptions to the above prohibitions may be authorized in the case of specific materials which has been so prepared, manufactured, or processed that in the judgment of the inspector no pest risk is involved in their entry.

* * * * *

§ 319.69–1 [Amended]

■ 6. Section 319.69–1 is amended by removing paragraph (b), and redesignating paragraph (c) as paragraph (b).

■ 7. Section 319.69–5 is amended by revising the section heading to read as follows:

§ 319.69–5 Types of organic decaying vegetative matter authorized for packing.

* * * * *

■ 8. Section 319.77–2 is amended as follows:

■ a. In paragraph (g), by removing the word "and";

■ b. By revising paragraph (h); and

■ c. By adding paragraph (i).

The addition and revision to read as follows:

§ 319.77–2 Regulated articles.

* * * * *

(h) Mobile homes and their associated equipment; and

(i) Stone and quarry products.

■ 9. Section 319.77–4 is amended by adding paragraph (d) to read as follows:

§ 319.77–4 Conditions for the importation of regulated articles.

* * * * *

(d) *Stone and quarry products.* Stone and quarry products originating in a Canadian infested area may be imported into the United States only if they are destined for an infested area of the United States and will not be moved through any noninfested areas of the United States, and may be moved through the United States if they are moved only through infested areas.

* * * * *

PART 330—FEDERAL PLANT PEST REGULATIONS; GENERAL; PLANT PESTS, BIOLOGICAL CONTROL ORGANISMS, AND ASSOCIATED ARTICLES; GARBAGE

■ 10. The authority citation for part 330 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

■ 11. The heading of part 330 is revised to read as set forth above.

■ 12. Section 330.100 is revised to read as follows:

§ 330.100 Definitions.

The following terms, when used in this part, shall be construed, respectively, to mean:

Administrative instructions. Published documents relating to the enforcement of this part, and issued under authority thereof by the Administrator.

Administrator. The Administrator of the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture, or any employee of APHIS to whom authority has been delegated to act in the Administrator's stead.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

Article. Any material or tangible object, including a living organism, that could harbor living plant pests or noxious weeds.

Biocontainment facility. A physical structure, or portion thereof, constructed and maintained in order to contain plant pests, biological control organisms, or associated articles.

Biological control organism. Any enemy, antagonist, or competitor used to control a plant pest or noxious weed.

Continental United States. The contiguous 48 States, Alaska, and the District of Columbia.

Department. The United States Department of Agriculture.

Deputy Administrator. The Deputy Administrator of the Plant Protection and Quarantine Programs or any employee of the Plant Protection and Quarantine Programs delegated to act in his or her stead.

Enter (entry). To move into, or the act of movement into, the commerce of the United States.

EPA. The Environmental Protection Agency of the United States.

Export (exportation). To move from, or the act of movement from, the United States to any place outside the United States.

Garbage. That material designated as "garbage" in § 330.400(b).

Hand-carry. Importation of an organism that remains in one's personal possession and in close proximity to one's person.

Import (importation). To move into, or the act of movement into, the territorial limits of the United States.

Inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of CBP to enforce the regulations in this part.

Interstate movement. Movement from one State into or through any other State; or movement within the District of Columbia, Guam, the U.S. Virgin Islands, or any other territory or possession of the United States.

Living. Viable or potentially viable.

Means of conveyance. Any personal or public property used for or intended for use for the movement of any other property. This specifically includes, but is not limited to, automobiles, trucks, railway cars, aircraft, boats, freight containers, and other means of transportation.

Move (moved and movement). To carry, enter, import, mail, ship, or transport; to aid, abet, cause, or induce the carrying, entering, importing, mailing, shipping, or transporting; to offer to carry, enter, import, mail, ship, or transport; to receive to carry, enter, import, mail, ship, or transport; to release into the environment, or to allow any of those activities.

Noxious weed. Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

Owner. The owner, or his or her agent, having possession of a plant pest, biological control organism, associated article, or any other means of conveyance, products, or article subject to the regulations in this part.

Permit. A written authorization, including by electronic methods, by the Administrator to move plant pests, biological control organisms, or associated articles under conditions prescribed by the Administrator.

Permittee. The person to whom APHIS has issued a permit in accordance with this part and who must comply with the provisions of the permit and the regulations in this part.

Person. Any individual, partnership, corporation, association, joint venture, or other legal entity.

Plant. Any plant (including any plant part) for or capable of propagation including trees, tissue cultures, plantlet cultures, pollen, shrubs, vines, cuttings, grafts, scions, buds, bulbs, roots, and seeds.

Plant pest. Any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

Plant product. Any flower, fruit, vegetable, root, bulb, seed, or other plant part that is not included in the definition of plant; or any manufactured or processed plant or plant part.

Plant Protection and Quarantine Programs. The Plant Protection and Quarantine Programs of the Animal and Plant Inspection Health Service.

Regulated garbage. That material designated as "regulated garbage" in § 330.400(c) and § 330.400(d).

Responsible individual. The individual who a permittee designates to oversee and control the actions taken under a permit issued in accordance with this part for the movement or curation of a plant pest, biological control organism, or associated article. For the duration of the permit, the individual must be physically present during normal business hours at or near the location specified on the permit as the ultimate destination of the plant pest, biological control organism, or associated article, and must serve as a primary contact for communication with APHIS. The permittee may designate him or herself as the responsible individual. The responsible individual must be at least 18 years of age. In accordance with section 7734 of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the act, omission, or failure of any responsible individual will also be deemed the act, omission, or failure of a permittee.

Secure shipment. Shipment of a regulated plant pest, biological control organism, or associated article in a container or a means of conveyance of sufficient strength and integrity to prevent leakage of contents and to withstand shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

Shelf-stable. The condition achieved in a product, by application of heat, alone or in combination with other ingredients and/or other treatments, of being rendered free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50 °F or 10 °C).

Soil. The unconsolidated material from the earth's surface that consists of rock and mineral particles and that supports or is capable of supporting biotic communities.

State. Any of the States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the U.S. Virgin Islands, and all other territories or possessions of the United States.

Sterilization (sterile, sterilized). A chemical or physical process that results in the death of all living organisms on or within the article subject to the process. Examples include, but are not limited to, autoclaving and incineration.

Taxon (taxa). Any recognized grouping or rank within the biological nomenclature of organisms, such as class, order, family, genus, species, subspecies, pathovar, biotype, race, forma specialis, or cultivar.

Transit. Movement from and to a foreign destination through the United States.

United States. All of the States.

U.S. Customs and Border Protection (CBP). U.S. Customs and Border Protection within the Department of Homeland Security.

■ 13. Subpart—Movement of Plant Pests, §§ 330.200 through 330.212, is revised to read as follows:

Subpart—Movement of Plant Pests, Biological Control Organisms, and Associated Articles

Sec.

Subpart—Movement of Plant Pests, Biological Control Organisms, and Associated Articles

§ 330.200 Scope and general restrictions.

(a) No person shall import, move interstate, transit, or release into the environment plant pests, biological control organisms, or associated articles, unless the importation, interstate movement, transit, or release into the environment of the plant pests, biological control organisms, or plant pests is:

(1) Authorized under an import, interstate movement, or continued curation permit issued in accordance with § 330.201; or

(2) Authorized in accordance with other APHIS regulations in this chapter; or

(3) Explicitly granted an exception or exemption in this subpart from permitting requirements; or

(4) Authorized under a general permit issued by the Administrator.

(b) *Plant pests regulated by this subpart.* For the purposes of this subpart, APHIS will consider an organism to be a plant pest if the organism directly or indirectly injures, causes damage to, or causes disease in a plant or plant product, or if the organism is an unknown risk to plants or plant products, but is similar to an organism known to directly or indirectly injure, cause damage to, or cause disease in a plant or plant product.

(c) *Biological control organisms regulated by this subpart.* For the purposes of this subpart, biological control organisms include:

(1) Invertebrate predators and parasites (parasitoids) used to control invertebrate plant pests,

(2) Invertebrate competitors used to control invertebrate plant pests,

(3) Invertebrate herbivores used to control noxious weeds,

(4) Microbial pathogens used to control invertebrate plant pests,

(5) Microbial pathogens used to control noxious weeds,

(6) Microbial parasites used to control plant pathogens, and

(7) Any other types of biological control organisms, as determined by APHIS.

(d) *Biological control organisms not regulated by this subpart.* The preceding paragraph notwithstanding, biological control organism-containing products that are currently under an EPA outdoor experimental use permit or that are currently registered with EPA as a microbial pesticide product having outdoor uses are not regulated under this subpart. Additionally, biological control organisms that are pesticides that are not registered with EPA, but are being transferred, sold, or distributed in accordance with EPA's regulations in 40 CFR 152.30, are not regulated under this subpart for their interstate movement or importation. However, an importer desiring to import a shipment of biological control organisms subject to the Federal Insecticide Fungicide and Rodenticide Act must submit to the EPA Administrator a Notice of Arrival of Pesticides and Devices as required by CBP regulations at 19 CFR 12.112. The Administrator will provide notification

to the importer indicating the disposition to be made of shipment upon its entry into the customs territory of the United States.

§ 330.201 Permit requirements.

(a) *Types of permits.* APHIS issues import permits, interstate movement permits, continued curation permits, and transit permits for plant pests, biological control organisms, and associated articles.[1]

(1) *Import permit.* Import permits are issued to persons for secure shipment from outside the United States into the territorial limits of the United States. When import permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States. When import permits are issued to corporate persons, these persons must maintain an address or business office in the United States with a designated individual for service of process.

(2) *Interstate movement permit.* Interstate movement permits are issued to persons for secure shipment from any State into or through any other State. When interstate movement permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States. When interstate movement permits are issued to corporate persons, these persons must maintain an address or business office in the United States with a designated individual for service of process.

(3) *Continued curation permits.* Continued curation permits are issued in conjunction with and prior to the expiration date for an import permit or interstate movement permit, in order for the permittee to continue the actions listed on the import permit or interstate movement permit. When continued curation permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States. When continued curation permits are issued to corporate persons, these persons must maintain an address or business office in the United States with a designated individual for service of process.

(4) *Transit permits.* Transit permits are issued for secure shipments through the United States. Transit permits are issued in accordance with part 352 of this chapter.

[1] Persons contemplating the shipment of plant pests, biological control organisms, or associated articles to places outside the United States should make arrangements directly, or through the recipient, with the country of destination for the export of the plant pests, biological control organisms, or associated articles into that country.

(b) *Applying for a permit.* Permit applications must be submitted by the applicant in writing or electronically through one of the means listed at *http://www.aphis.usda.gov/plant_health/permits/index.shtml* in advance of the action(s) proposed on the permit application.

(c) *Completing a permit application.* A permit application must be complete before APHIS will evaluate it in order to determine whether to issue the permit requested. Guidance regarding how to complete a permit application, including guidance specific to the various information blocks on the application, is available at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.*

(d) *APHIS action on permit applications.* APHIS will review the information on the application to determine whether it is complete. In order to consider an application complete, APHIS may request additional information that it determines to be necessary in order to assess the risk to plants and plant products that may be posed by the actions proposed on the application. When it is determined that an application is complete, APHIS will commence review of the information provided.

(1) *State or Tribal consultation and comment; consultation with other individuals.* APHIS will share a copy of the permit application, and the proposed permit conditions, with the appropriate State or Tribal regulatory officials, and may share the application and the proposed conditions with other persons or groups to provide comment.

(2) *Initial assessment of sites and facilities.* Prior to issuance of a permit, APHIS will assess all sites and facilities that are listed on the permit application, including private residences, biocontainment facilities, and field locations where the organism or article will be held or released. As part of this assessment, all sites and facilities are subject to inspection. All facilities must be determined by APHIS to be constructed and maintained in a manner that prevents the dissemination or dispersal of plant pests, biological control organisms, or associated articles from the facility. The applicant must provide all information requested by APHIS regarding this assessment, and must allow all inspections requested by APHIS during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, excluding holidays). Failure to do so constitutes grounds for denial of the permit application.

(3) *Issuance of a permit.* APHIS may issue a permit to an applicant if APHIS concludes that the actions allowed under the permit will be highly unlikely to result in the introduction or dissemination of a plant pest, biological control organism, or noxious weed within the United States in a manner that presents an unacceptable risk to plants and plant products. Issuance will occur as follows:

(i) Prior to issuing the permit, APHIS will notify the applicant in writing or electronically of all proposed permit conditions. The applicant must agree in writing or electronically that he or she, and all his or her employees, agents, and/or officers, will comply with all permit conditions and all provisions of this subpart. If the organism or associated article will be contained in a private residence, the applicant must state in this agreement that he or she authorizes APHIS to conduct unscheduled assessments of the residence during normal business hours if a permit is issued.

(ii) APHIS will issue the permit after it receives and reviews the applicant's agreement. The permit will be valid for no more than 3 years. During that period, the permittee must abide by all permitting conditions, and the use of the organism or article must conform to the intended use on the permit. Moreover, the use of organisms derived from a regulated parent organism during that period must conform to the intended use specified on the permit for the parent organism.

(iii) All activities carried out under the permit must cease on or before the expiration date for the permit, unless, prior to that expiration date, the permittee has submitted a new permit application and a new permit has been issued to authorize continuation of those actions.

(iv) At any point following issuance of a permit but prior to its expiration date, an inspector may conduct unscheduled assessments of the site or facility in which the organisms or associated articles are held, to determine whether they are constructed and are being maintained in a manner that prevents the dissemination of organisms or associated articles from the site or facility. The permittee must allow all such assessments requested by APHIS during normal business hours. Failure to allow such assessments constitutes grounds for revocation of the permit.

(4) *Denial of a permit application.* APHIS may deny an application for a permit if:

(i) APHIS concludes that the actions proposed in the permit application would present an unacceptable risk to plants and plant products because of the introduction or dissemination of a plant

pest, biological control organism, or noxious weed within the United States; or

(ii) The actions proposed in the permit application would be adverse to the conduct of an APHIS eradication, suppression, control, or regulatory program; or

(iii) A State or Tribal executive official, or a State or Tribal plant protection official authorized to do so, objects to the movement in writing and provides specific, detailed information that there is a risk the movement will result in the dissemination of a plant pest or noxious weed into the State, APHIS evaluates the information and agrees, and APHIS determines that such plant pest or noxious weed risk cannot be adequately addressed or mitigated; or

(iv) The applicant does not agree to observe all of the proposed permit conditions that APHIS has determined are necessary to mitigate identified risks; or

(v) The applicant does not provide information requested by APHIS as part of an assessment of sites or facilities, or does not allow APHIS to inspect sites or facilities associated with the actions listed on the permit application; or

(vi) APHIS determines that the applicant has not followed prior permit conditions, or has not adequately demonstrated that they can meet the requirements for the current application. Factors that may contribute to such a determination include, but are not limited to:

(A) The applicant, or a partnership, firm, corporation, or other legal entity in which the applicant has a substantial interest, financial or otherwise, has not complied with any permit that was previously issued by APHIS.

(B) Issuing the permit would circumvent any order denying or revoking a previous permit issued by APHIS.

(C) The applicant has previously failed to comply with any APHIS regulation.

(D) The applicant has previously failed to comply with any other Federal, State, or local laws, regulations, or instructions pertaining to plant health.

(E) The applicant has previously failed to comply with the laws or regulations of a national plant protection organization or equivalent body, as these pertain to plant health.

(F) APHIS has determined that the applicant has made false or fraudulent statements or provided false or fraudulent records to APHIS.

(G) The applicant has been convicted or has pled *nolo contendere* to any crime involving fraud, bribery, extortion, or any other crime involving a lack of integrity.

(5) *Withdrawal of a permit application.* Any permit application may be withdrawn at the request of the applicant. If the applicant wishes to withdraw a permit application, he or she must provide the request in writing to APHIS. APHIS will provide written notification to the applicant as promptly as circumstances allow regarding reception of the request and withdrawal of the application.

(6) *Cancellation of a permit.* Any permit that has been issued may be canceled at the request of the permittee. If a permittee wishes a permit to be canceled, he or she must provide the request in writing to APHIS–PPQ. Whenever a permit is canceled, APHIS will notify the permittee in writing regarding such cancellation.

(7) *Revocation of a permit.* APHIS may revoke a permit for any of the following reasons:

(i) After issuing the permit, APHIS obtains information that would have otherwise provided grounds for it to deny the permit application; or

(ii) APHIS determines that the actions undertaken under the permit have resulted in or are likely to result in the introduction into or dissemination within the United States of a plant pest or noxious weed in a manner that presents an unacceptable risk to plants or plant products; or

(iii) APHIS determines that the permittee, or any employee, agent, or officer of the permittee, has failed to comply with a provision of the permit or the regulations under which the permit was issued.

(8) *Amendment of permits.* (i) *Amendment at permittee's request.* If a permittee determines that circumstances have changed since the permit was initially issued and wishes the permit to be amended accordingly, he or she must request the amendment, either through APHIS' online portal for permit applications, or by contacting APHIS directly via phone or email. The permittee may have to provide supporting information justifying the amendment. APHIS will review the amendment request, and may amend the permit if only minor changes are necessary. Requests for more substantive changes may require a new permit application. Prior to issuance of an amended permit, the permittee may be required to agree in writing that he or she, and his or her employees, agents, and/or officers will comply with the amended permit and conditions.

(ii) *Amendment initiated by APHIS.* APHIS may amend any permit and its conditions at any time, upon determining that the amendment is needed to address newly identified considerations concerning the risks presented by the organism or the activities being conducted under the permit. APHIS may also amend a permit at any time to ensure that the permit conditions are consistent with all of the requirements of this part. As soon as circumstances allow, APHIS will notify the permittee of the amendment to the permit and the reason(s) for it. Depending on the nature of the amendment, the permittee may have to agree in writing or electronically that he or she, and his or her employees, agents, and/or officers, will comply with the permit and conditions as amended before APHIS will issue the amended permit. If APHIS requests such an agreement, and the permittee does not agree in writing that he or she, and his or her employees, agents, and/or officers, will comply with the amended permit and conditions, the existing permit will be revoked.

(9) *Suspension of permitted actions.* APHIS may suspend authorization of actions authorized under a permit if it identifies new factors that cause it to reevaluate the risk associated with those actions. APHIS will notify the permittee in writing of this suspension explaining the reasons for it and stating the actions for which APHIS is suspending authorization. Depending on the results of APHIS' evaluation, APHIS will subsequently contact the permittee to remove the suspension, amend the permit, or revoke the permit.

(10) *Appeals.* Any person whose application has been denied, whose permit has been revoked or amended, or whose authorization for actions authorized under a permit has been suspended, may appeal the decision in writing to the Administrator within 10 business days after receiving the written notification of the denial, revocation, amendment, or suspension. The appeal shall state all of the facts and reasons upon which the person relies to show that the application was wrongfully denied, permit revoked or amended, or authorization for actions under a permit suspended. The Administrator shall grant or deny the appeal, stating the reasons for the decision as promptly as circumstances allow.

§ 330.202 Biological control organisms.

(a) *General conditions for importation, interstate movement, and environmental release of biological control organisms.* Except as provided in paragraph (b) of this section, no biological control organism regulated under this subpart may be imported, moved interstate, or released into the

environment unless a permit has been issued in accordance with § 330.201 authorizing such importation, interstate movement, or environmental release, and the organism is moved or released in accordance with this permit and the regulations in this subpart. The regulations in 40 CFR parts 1500–1508, 7 CFR part 1b, and 7 CFR part 372 may require APHIS to request additional information from an applicant regarding the proposed release of a biological control organism as part of its evaluation of a permit application. Further information regarding the types of information that may be requested, and the manner in which this information will be evaluated, is found at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.*

(b) *Exceptions from permitting requirements for certain biological control organisms.* APHIS has determined that certain biological control organisms have become established throughout their geographical or ecological range in the continental United States, such that the additional release of pure cultures derived from field populations of taxa of such organisms into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products. A list of these organisms is maintained online, at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.*

(1) *Importation and interstate movement of listed organisms.* Pure cultures of organisms on the list may be imported into or moved interstate within the continental United States without further restriction under this subpart.

(2) *Environmental release of listed organisms.* Pure cultures of organisms on the list may be released into the environment of the continental United States without further restriction under this subpart.

(c) *Additions to the list of organisms granted exceptions from permitting requirements for their importation or interstate movement.* Any person may request that APHIS add a biological control organism to the list referred to in paragraph (b) of this section by submitting a petition to APHIS via email to *pest.permits@aphis.usda.gov* or through any means listed at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.* The petition must include the following information:

(1) Evidence indicating that the organism is indigenous to the continental United States throughout its geographical or ecological range, or evidence indicating that the organism has produced self-replicating populations within the continental United States for an amount of time sufficient, based on the organism's taxon, to consider that taxon established throughout its geographical or ecological range in the continental United States.

(2) Results from a field study where data was collected from representative habitats occupied by the biological control organism. Studies must include sampling for any direct or indirect impacts on target and non-target hosts of the biological control organism in these habitats. Supporting scientific literature must be cited.

(3) Any other data, including published scientific reports, that suggest that subsequent releases of the organism into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products.

(d) *APHIS review of petitions.* (1) APHIS will review the petition to determine whether it is complete. If APHIS determines that the petition is complete, it will conduct an evaluation of the petition to determine whether there is sufficient evidence that the organism exists throughout its geographical or ecological range in the continental United States and that subsequent releases of pure cultures of field populations of the organism into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products.

(2) *Notice of availability of the petition.* If APHIS determines that there is sufficient evidence that the organism exists throughout its geographical or ecological range in the continental United States and that subsequent releases of pure cultures of the organism into the environment of the continental United States will present no additional plant pest risk to plants or plant products, APHIS will publish a notice in the **Federal Register** announcing the availability of the petition and requesting public comment on that document.

(3) *Notice of determination.* (i) If no comments are received, or if the comments received do not lead APHIS to reconsider its determination, APHIS will publish in the **Federal Register** a subsequent notice describing the comments received and stating that the organism has been added to the list referred to in paragraph (b) of this section.

(ii) If the comments received lead APHIS to reconsider its determination, APHIS will publish in the **Federal Register** a subsequent notice describing the comments received and stating its reasons for determining not to add the organism to the list referred to in paragraph (b) of this section.

(e) *Removal of organisms from the list of exempt organisms.* Any biological control organism may be removed from the list referred to in paragraph (b) of this section if information emerges that would have otherwise led APHIS to deny the petition to add the organism to the list. Whenever an organism is removed from the list, APHIS will publish a notice in the **Federal Register** announcing that action and the basis for it.

§ 330.203 Soil.

(a) The Administrator has determined that, unless it has been sterilized, soil is an associated article, and is thus subject to the permitting requirements of § 330.201, unless its movement:

(1) Is regulated pursuant to other APHIS regulations in this chapter; or

(2) Does not require such a permit under the provisions of paragraphs (b)(1) or (c)(1) of this section.

(b) *Conditions governing the importation of soil.*

(1) *Permit.* Except as provided in § 319.37–8(b)(2) of this chapter and except for soil imported from areas of Canada other than those areas of Canada regulated by the national plant protection organization of Canada for a soil-borne plant pest, soil may only be imported into the United States if an import permit has been issued for its importation in accordance with § 330.201, and the soil will be imported under the conditions specified on the permit.

(2) *Additional conditions for the importation of soil via hand-carry.* In addition to the condition of paragraph (b)(1) of this section, soil may be hand-carried into the United States only if the importation meets the conditions of § 330.205.

(3) *Additional conditions for the importation of soil intended for the extraction of plant pests.* In addition to the condition of paragraph (b)(1) of this section, soil may be imported into the United States for the extraction of plant pests if the soil will be imported directly to a biocontainment facility approved by APHIS.

(4) *Additional conditions for the importation of soil contaminated with plant pests and intended for disposal.* In addition to the condition of paragraph (b)(1) of this section, soil may be imported into the United States for the disposal of plant pests if the soil will be imported directly to an APHIS-approved disposal facility.

(5) *Exemptions.* The articles listed in this paragraph are not soil, provided that they are free of organic material. Therefore, they may be imported into the United States without an import permit issued in accordance with § 330.201, unless the Administrator has issued an order stating that a particular article is an associated article. All such articles are, however, subject to inspection at the port of first arrival, subsequent reinspection at other locations, other remedial measures deemed necessary by an inspector to remove any risk the items pose of disseminating plant pests or noxious weeds, and any other restrictions of this chapter:

(i) Consolidated material derived from any strata or substrata of the earth. Examples include clay (laterites, bentonite, china clay, attapulgite, tierrafino), talc, chalk, slate, iron ore, and gravel.

(ii) Sediment, mud, or rock from saltwater bodies of water.

(iii) Cosmetic mud and other commercial mud products.

(iv) Stones, rocks, and quarry products.

(c) *Conditions governing the interstate movement of soil.* (1) *General conditions.* Except for soil moved in accordance with paragraphs (c)(2) through (5) of this section, soil may be moved interstate within the United States without prior issuance of an interstate movement permit in accordance with § 330.201 or further restriction under this subpart. However, all soil moved interstate is subject to any movement restrictions and remedial measures specified for such movement in part 301 of this chapter.

(2) *Conditions for the interstate movement within the continental United States of soil intended for the extraction of plant pests.* Soil may be moved interstate within the continental United States with the intent of extracting plant pests, only if an interstate movement permit has been issued for its movement in accordance with § 330.201, and the soil will be moved directly to a biocontainment facility approved by APHIS in a secure manner that prevents its dissemination into the outside environment.

(3) *Conditions for the interstate movement within the continental United States of soil infested with plant pests and intended for disposal.* Soil may be moved interstate within the continental United States with the intent of disposing of plant pests, only if an interstate movement permit has been issued for its movement in accordance with § 330.201, and the soil will be moved directly to an APHIS-approved disposal facility in a secure manner that prevents its dissemination into the outside environment.

(4) *Conditions for the interstate movement of soil samples from an area quarantined in accordance with part 301 of this chapter for chemical or compositional testing or analysis.* Soil samples may be moved for chemical or compositional testing or analysis from an area that is quarantined in accordance with part 301 of this chapter without prior issuance of an interstate movement permit in accordance with § 330.201 or further restriction under this chapter, provided that the soil is moved to a laboratory that has entered into and is operating under a compliance agreement with APHIS, is abiding by all terms and conditions of the compliance agreement, and is approved by APHIS to test and/or analyze such samples.

(5) *Additional conditions for interstate movement of soil to, from, or between Hawaii, the territories, and the continental United States.* In addition to all general conditions for interstate movement of soil, soil may be moved interstate to, from, or between Hawaii, the territories, and the continental United States only if an interstate movement permit has been issued for its movement in accordance with § 330.201. In addition, soil moved to, from, or between Hawaii, the territories, and the continental United States with the intent of extracting plant pests is subject to the conditions of paragraph (c)(2) of this section, while soil infested with plant pests and intended for disposal is subject to the conditions of paragraph (c)(3) of this section.

(d) *Conditions governing the transit of soil through the United States.* Soil may transit through the United States only if a transit permit has been issued for its movement in accordance with part 352 of this chapter.

§ 330.204 Exceptions to permitting requirements for the importation or interstate movement of certain plant pests.

Pursuant to section 7711 of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the Administrator has determined that certain plant pests may be imported into or may move in interstate commerce within the continental United States without restriction. The list of all such plant pests is listed on the Internet at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.*

(a) *Categories.* In order to be included on the list, a plant pest must:

(1) Be from field populations or lab cultures derived from field populations of a taxon that established throughout its entire geographical or ecological range within the continental United States; or

(2) Be sufficiently attenuated so that it no longer poses a risk to plants or plant products; or

(3) Be commercially available and raised under the regulatory purview of other Federal agencies.

(b) *Petition process to add plant pests to the list.* (1) *Petition.* Any person may petition APHIS to have an additional plant pest added to the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction. To submit a petition, the person must provide, in writing, information supporting the placement of a particular pest in one of the categories listed in paragraph (a) of this section.

(i) Information that the plant pest belongs to a taxon that is established throughout its entire geographical or ecological range within the United States must include scientific literature, unpublished studies, or data regarding:

(A) The biology of the plant pest, including characteristics that allow it to be identified, known hosts, and virulence;

(B) The geographical or ecological range of the plant pest within the continental United States; and

(C) The areas of the continental United States within which the plant pest is established.

(ii) Information that the plant pest has been attenuated of its pathogenicity must include experimental data, published references, or scientific information regarding such attenuation.

(iii) Information that the plant pest is commercially available and raised under the regulatory purview of another Federal agency must include a citation to the relevant law, regulation, or order under which the agency exercises such oversight.

(2) *APHIS review.* APHIS will review the information contained in the petition to determine whether it is complete. In order to consider the petition complete, APHIS may require additional information to determine whether the plant pest belongs to one of the categories listed in paragraph (a) of this section. When it is determined that the information is complete, APHIS will commence review of the petition.

(3) *Action on petitions to add pests.* (i) If, after review of the petition, APHIS determines there is insufficient evidence that the plant pest belongs to one of the three categories listed in paragraph (a) of this section, APHIS will deny the petition, and notify the petitioner in writing regarding this denial.

(ii) If, after review of the petition, APHIS determines that the plant pest belongs to one of the categories in paragraph (a) of this section, APHIS will publish a notice in the **Federal Register** that announces the availability of the petition and any supporting documentation to the public, that states that APHIS intends to add the plant pest to the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction, and that requests public comment. If no comments are received on the notice, or if, based on the comments received, APHIS determines that its conclusions regarding the petition have not been affected, APHIS will publish in the **Federal Register** a subsequent notice stating that the plant pest has been added to the list.

(c) *Petition process to have plant pests removed from the list.* (1) *Petition.* Any person may petition to have a plant pest removed from the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction by writing to APHIS. The petition must contain independently verifiable information demonstrating that APHIS' initial determination that the plant pest belongs to one of the categories in paragraph (a) of the section should be changed, or that additional information is now available that would have caused us to change the initial decision.

(2) *APHIS review.* APHIS will review the information contained in the petition to determine whether it is complete. In order to consider the petition complete, APHIS may require additional information supporting the petitioner's claim. When it is determined that the information is complete, APHIS will commence review of the petition.

(3) *APHIS action on petitions to remove pests.* (i) If, after review of the petition, APHIS determines that there is insufficient evidence to suggest that its initial determination should be changed, APHIS will deny the petition, and notify the petitioner in writing regarding this denial.

(ii) If, after review of the petition, APHIS determines that there is a sufficient basis to suggest that its initial determination should be changed, APHIS will publish a notice in the **Federal Register** that announces the availability of the petition, and that requests public comment regarding removing the plant pest from the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction. If no comments are received on the notice, or if the comments received do not affect APHIS' conclusions regarding the petition, APHIS will publish a subsequent notice in the **Federal Register** stating that the plant pest has been removed from the list.

(d) *APHIS-initiated changes to the list.* (1) APHIS may propose to add a plant pest to or remove a pest from the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction without a petition, if it determines that there is sufficient evidence that the plant pest belongs to one of the categories listed in paragraph (a) of the section, or if evidence emerges that leads APHIS to reconsider its initial determination that the plant pest was or was not in one of the categories lists in paragraph (a) of this section. APHIS will publish a notice in the **Federal Register** announcing this proposed addition or removal, making available any supporting documentation that it prepares, and requesting public comment.

(2) If no comments are received on the notice or if the comments received do not affect the conclusions of the notice, APHIS will publish a subsequent notice in the **Federal Register** stating that the plant pest has been added to or removed from the list.

§ 330.205 Hand-carry of plant pests, biological control organisms, and soil.

Plant pests, biological control organisms, and soil may be hand-carried into the United States only in accordance with the provisions of this section.

(a) *Authorization to hand-carry.*

(1) *Application for a permit; specification of "hand-carry" as proposed method of movement.* A person must apply for an import permit for the plant pest, biological control organism, or soil, in accordance with § 330.201, and specify hand-carry of the organism or article as the method of proposed movement.

(2) *Specification of individual who will hand-carry.* The application must also specify the individual or individuals who will hand-carry the plant pest, biological control organism, or soil into the United States. If APHIS authorizes this individual or these individuals to hand-carry, the authorization may not be transferred to, nor actions under it performed by, individuals other than those identified on the permit application.

(b) *Notification of intent to hand-carry.* After the permittee has obtained an import permit but no less than 20 days prior to movement, the permittee must notify APHIS through APHIS' online portal for permit applications or by fax and provide the following information in order to receive a hand-carry shipping authorization:

(1) A copy of the face page of the passport for the individual or individuals who will hand-carry the plant pest, biological control organism, or soil;

(2) A description of the means of conveyance in which the individual or individuals will travel, including flight number and airline name for air travel, or vehicle license number or other identifying number for other modes of transportation;

(3) Expected date and time of first arrival;

(4) Expected port of first arrival; and

(5) Travel itinerary from port of first arrival to final destination.

(c) *Notification of arrival at the facility or point of destination.* The permittee or his or her designee must notify APHIS within 24 hours of arrival of the hand-carried plant pest, biological control organism, or soil at the biocontainment facility or other authorized point of destination. This notification must state that the plant pest, biological control organism, or soil has arrived at its destination and that the package in which it was hand-carried has remained sealed until arrival. Notification must be by fax or email, or via the Internet at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.*

(d) *Denial, amendment, or cancellation of authorization to hand-carry.* APHIS may deny a request to hand-carry, or amend or cancel any hand-carry authorization at any time, if it deems such action necessary to prevent the introduction or dissemination of plant pests or noxious weeds within the United States.

(e) *Appeal of denial, amendment, or cancellation.* Any person whose request to hand-carry has been denied, or whose authorization to hand-carry has been amended or canceled, may appeal the decision in writing to APHIS.

§ 330.206 Packaging requirements.

Shipments in which plant pests, biological control organisms, and associated articles are imported into, moved interstate, or transited through the United States must meet the general packaging requirements of this section, as well as all specific packaging requirements on the permit itself.

(a) *Packaging requirements.* All shipments must consist of an outer shipping container and at least two packages within the container. Both the

container and inner packages must be securely sealed to prevent the dissemination of the enclosed plant pests, biological control organisms, or associated articles.

(1) *Outer shipping container.* The outer shipping container must be rigid, impenetrable and durable enough to remain closed and structurally intact in the event of dropping, lateral impact with other objects, and other shocks incidental to handling.

(2) *Inner packages.* The innermost package or packages within the shipping container must contain all of the organisms or articles that will be moved. As a safeguard, the innermost package must be placed within another, larger package. All packages within the shipping container must be constructed or safeguarded so that they will remain sealed and structurally intact throughout transit. The packages must be able to withstand changes in pressure, temperature, and other climatic conditions incidental to shipment.

(b) *Packing material.* Packing material must be free of plant pests, noxious weeds, or associated articles, and must be new, or must have been sterilized or disinfected prior to reuse. Packing material must be suited for the enclosed organism or article, as well as any medium in which the organism or article will be maintained, and should not be capable of harboring or being a means of the dissemination of the organism or article.[2]

(c) *Requirements following receipt of the shipment at the point of destination.* (1) Packing material, including media and substrates, must be destroyed by incineration, be decontaminated using autoclaving or another approved method, or otherwise be disposed of in a manner specified in the permit itself.

(2) Shipping containers may not be reused, except those that have been sterilized or disinfected prior to reuse.

(d) *Costs.* Permittees who fail to meet the requirements of this section may be held responsible for all costs incident to inspection, rerouting, repackaging, subsequent movement, and any treatments.

§ 330.207 Cost and charges.

The inspection services of APHIS inspectors during regularly assigned hours of duty and at the usual places of duty will be furnished without cost. APHIS will not be responsible for any costs or charges incidental to inspections or compliance with the provisions of this subpart, other than for the inspection services of the inspector.

[2] Guidance regarding suitable outer shipping containers, inner packages, and packaging is provided at *http://www.aphis.usda.gov/plant_health/permits/index.shtml.*

Subpart—Movement of Soil, Stone, and Quarry Products [Removed and Reserved]

■ 14. Subpart—Movement of Soil, Stone, and Quarry Products, §§ 330.300 through 330.302, is removed and reserved.

PART 352—PLANT QUARANTINE SAFEGUARD REGULATIONS

■ 15. The authority citation continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

■ 16. In § 352.1, paragraph (b) is amended by adding, in alphabetical order, definitions for *biological control organism* and *noxious weed,* and by revising the definitions for *Deputy Administrator, person, plant pest,* and *soil* to read as follows:

§ 352.1 Definitions.

* * * * *

(b) * * *

Biological control organism. Any enemy, antagonist, or competitor used to control a plant pest or noxious weed.

* * * * *

Deputy Administrator. The Deputy Administrator of the Plant Protection and Quarantine Programs or any employee of the Plant Protection and Quarantine Programs delegated to act in his or her stead.

* * * * *

Noxious weed. Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

* * * * *

Person. Any individual, partnership, corporation, association, joint venture, society, or other legal entity.

Plant pest. Any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the above.

* * * * *

Soil. The unconsolidated material from the earth's surface that consists of rock and mineral particles and that supports or is capable of supporting biotic communities.

* * * * *

§ 352.2 [Amended]

■ 17. In § 352.2, paragraph (a) introductory text, the first sentence is amended by removing the words "plant pests, noxious weeds, soil," and adding the words "plant pests, biological control organisms, noxious weeds, soil," in their place, and by removing the words "contain plant pests or noxious weeds" and adding the words "contain plant pests, biological control organisms, or noxious weeds" in their place.

§ 352.3 [Amended]

■ 18. In § 352.3, paragraph (a) is amended by adding the words "biological control organisms," after the words "plant pests," each time they occur.

§ 352.5 [Amended]

■ 19. Section 352.5 is amended by adding the words "biological control organisms," after the words "plant pests," each time they occur.

§ 352.6 [Amended]

■ 20. Section 352.6 is amended as follows:

■ a. By removing footnote 2;

■ b. In paragraph (b), by removing the words "as specified by" and adding the words "in accordance with" in their place; and

■ c. In paragraph (c), by removing the citation "§ 330.300(b)" and adding the citation "§ 330.203" in its place.

§ 352.9 [Amended]

■ 21. Section 352.9 is amended by adding the words "biological control organisms," after the words "plant pests,".

§ 352.10 [Amended]

■ 22. Section 352.10 is amended as follows:

■ a. By redesignating footnote 3 as footnote 2;

■ b. By removing the words "plant pest or noxious weed dissemination" each time they occur and adding the words "plant pest, noxious weed, or biological control organism dissemination" in their place;

■ c. In paragraph (b)(1), by adding the words "biological control organisms," after the words "Prohibited or restricted plants, plant products, plant pests,";

■ d. In paragraph (b)(2)(i), by adding the words "or biological control organisms," after the words "plant pests";

■ e. In paragraph (b)(2)(ii), by adding the words "biological control organisms," after the words "plant pests,"; and
■ f. In paragraph (b)(2)(iv), by removing the words "plant pest dispersal" and adding the words "plant pest or biological control organism dispersal" in their place.

§ 352.11 [Amended]

■ 23. In § 352.11, paragraph (a)(1) is amended by adding the words "biological control organisms," after the words "plant pests,".

§ 352.13 [Amended]

■ 24. Section 352.13 is amended by adding the words "biological control organisms," after the words "plant pests,".

§ 352.30 [Amended]

■ 25. Section 352.30 is amended by redesignating footnotes 4 and 5 as footnotes 3 and 4, respectively.

Done in Washington, DC, this 6th day of January 2017.

David Howard,

Acting Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2017–00532 Filed 1–18–17; 8:45 am]

BILLING CODE 3410–34–P

electronically at: *https://www.epa.gov/air-emissions-factors-and-quantification/new-and-revised-emissions-factors-flares-and-new-emissions.*

FOR FURTHER INFORMATION CONTACT: Ms. Gerri Garwood, Measurement Policy Group (MPG), Sector Policies and Programs Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number: (919) 541–2406; fax number: (919) 541–1039; and email address: *garwood.gerri@epa.gov.*

SUPPLEMENTARY INFORMATION: As described above, the EPA finalized these actions to fulfill its obligations under a settlement agreement, which resolves a petition for judicial review on actions the EPA took on April 20, 2015. On April 20, 2015, the EPA issued new and revised emissions factors for flares and other refinery process units and issued its final determination that revisions to existing emissions factors for tanks and wastewater treatment systems were not necessary in order to fulfill its obligations under a consent decree. Plaintiffs alleged that the EPA failed to perform nondiscretionary duties pursuant to Clean Air Act (CAA) section 130 to review, and, if necessary, revise the emissions factors for volatile organic compounds (VOC) for flares, liquid storage tanks (''tanks''), and wastewater collection, treatment and storage systems (''wastewater treatment systems'') at least once every 3 years. See *Air Alliance Houston, et al.* v. *EPA,* Case No. 15–1210 (D.C. Cir.) and *Air Alliance Houston, et al.* v. *McCarthy,* No. 1:13–cv–00621–KBJ (D.D.C.).

The settlement agreement outlined 20 specific Source Classification Codes (SCCs) that Plaintiffs argued should be included in Tables 13.5–1 and 13.5–2 of AP–42, *Compilation of Air Pollutant Emission Factors.* AP–42 is the primary compilation of EPA's emissions factor information. Additionally, Plaintiffs sought minor clarifications to the text in Section 13.5 of AP–42, as well as an update to the VOC emissions factor due to errors in the original calculation.

Per the requirements of the settlement agreement, this final action was issued by December 16, 2016. To support this action, we developed a memorandum to document our determinations in regards to the 20 SCCs specified in the settlement agreement. We also revised section 13.5 of AP–42, the supporting background documentation, and the previously issued report, *Review of Emissions Test Reports for Emissions Factors Development for Flares and Certain Refinery Operations.* The SCC determination memorandum and the revised report, along with a link to the updated section in AP–42 and supporting background documentation, were posted on the Web site listed in the **ADDRESSES** section of this document on December 14, 2016.

These actions constitute final agency action of national applicability for purposes of section 307(b)(1) of the CAA. Pursuant to CAA section 307(b)(1), judicial review of these final agency actions may be sought only in the United States Court of Appeals for the District of Columbia Circuit. Petitions for review must be filed by March 24, 2017. Judicial review of these final agency actions may not be obtained in subsequent proceedings, pursuant to CAA section 307(b)(2). These actions are not a rulemaking and are not subject to the various statutory and other provisions applicable to a rulemaking.

Dated: January 13, 2017.

Stephen Page,

Director, Office of Air Quality Planning and Standards.

[FR Doc. 2017–01263 Filed 1–19–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9031–4]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements

Filed 01/09/2017 Through 01/13/2017 Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20170011, Draft, APHIS, Other, Revisions to USDA–APHIS 7 CFR part 340 Regulations Governing the Importation, Interstate Movement, and Environmental Release of Genetically Engineered Organisms, Comment Period Ends: 05/22/2017, Contact: Cindy Eck 301–851–3892.

EIS No. 20170012, Final, TVA, TN, Bull Run Fossil Plant Landfill, Review Period Ends: 02/21/2017, Contact: Anita E. Masters 423–751–8697.

EIS No. 20170013, Final, NPS, CA, Alcatraz Ferry Embarkation, Review Period Ends: 02/21/2017, Contact: Brian Aviles 415–561–4942.

EIS No. 20170014, Draft, APHIS, Other, Regulation of the Importation, Interstate Movement, and Intrastate Movement of Plant Pests, Comment Period Ends: 03/20/2017, Contact: Tracy Willard 301–851–3101.

EIS No. 20170015, Final, USFS, AZ, Camp Tatiyee Land Exchange, Review Period Ends: 02/21/2017, Contact: Randall Chavez 928–368–2106.

Amended Notices

EIS No. 20160263, Draft, USN, WA, EA–18G ''Growler'' Airfield Operations at the NAS Whidbey Island Complex, Comment Period Ends: 02/24/2017, Contact: Sarah Stallings 757–322–4733.

Revision to FR Notice Published 11/10/2016; Extending Comment Period from 01/25/2017 to 02/24/2017.

EIS No. 20160274, Draft, FHWA, NY, NYS Route 198 (Scajaquada Expressway) Corridor Project, Comment Period Ends: 01/25/2017, Contact: Peter Osborn 518–431–4127.

Revision to FR Notice Published 11/25/2016; Extending Comment Period from 01/25/2017 to 02/08/2017.

EIS No. 20160319, Draft, BLM, CA, Central Coast Field Office Draft Resource Management Plan Amendment for the Oil and Gas Leasing and Development, Comment Period Ends: 04/06/2017, Contact: Melinda Moffitt 916–978–4376.

Revision to FR Notice Published 01/06/2017; Extending Comment Period from 02/21/2017 to 04/06/2017.

Dated: January 17, 2017.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2017–01426 Filed 1–19–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2013–0310; FRL–9955–64–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Sewage Sludge Treatment Plants (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information

Proposed Rules

Federal Register
Vol. 82, No. 28
Monday, February 13, 2017

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 318, 319, 330, and 352

[Docket No. APHIS–2008–0076]

RIN 0579–AC98

Plant Pest Regulations; Update of Provisions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; extension of comment period.

SUMMARY: We are extending the comment period for our proposed rule that would revise our regulations regarding the movement of plant pests to propose criteria regarding the movement and environmental release of biological control organisms, and to establish regulations to allow the importation and movement in interstate commerce of certain types of plant pests without restriction by granting exceptions from permitting requirements for those pests. The proposal would also revise our regulations regarding the movement of soil. This action will allow interested persons additional time to prepare and submit comments.

DATES: The comment period for the proposed rule published on January 19, 2017 (82 FR 6980) is extended. We will consider all comments that we receive on or before April 19, 2017.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0076.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2008–0076, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0076* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Colin D. Stewart, Assistant Director, Pests, Pathogens, and Biocontrol Permits Branch, Plant Health Programs, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737–1236; (301) 851–2237.

SUPPLEMENTARY INFORMATION:

On January 19, 2017, we published in the **Federal Register** (82 FR 6980–7005, Docket No. APHIS–2008–0076) a proposal to revise our regulations regarding the movement of plant pests to propose criteria regarding the movement and environmental release of biological control organisms and to establish regulations to allow the importation and movement in interstate commerce of certain types of plant pests without restriction by granting exceptions from permitting requirements for those pests. We also proposed to revise our regulations regarding the movement of soil.

Comments on the proposed rule were required to be received on or before March 20, 2017. We are extending the comment period on Docket No. APHIS–2008–0076 for an additional 30 days. This action will allow interested persons additional time to prepare and submit comments.

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 7th day of February 2017.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–02871 Filed 2–10–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0330]

RIN 1625–AA09

Drawbridge Operation Regulation; Gulf Intracoastal Waterway, Sarasota, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to modify the operating schedule of four bridges across the Gulf Intracoastal Waterway; Stickney Point, mile 68.6, Siesta Drive, mile 71.6, Cortez, mile, 87.4 and Anna Maria, mile 89.2, Drawbridges, Sarasota, FL. The request was made to the Coast Guard to change the operation of four drawbridges due to an increase in vehicle traffic throughout these areas at all times of the year. This proposed rulemaking would change the bridges' operating schedule from a three times an hour opening schedule to a twice an hour opening schedule throughout the year.

DATES: All comments and related material must be received by the Coast Guard on or before April 14, 2017.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0330 using Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rule, call or email, LT Ashley Holm, Coast Guard Sector St Petersburg, Florida; telephone (813) 228–2191 x8105, email *Ashley.E.Holm@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

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Appendix F. Acronyms and Glossary

A

Acari	Taxonomic group of organisms that includes mites and ticks.
APHIS	Animal and Plant Health Inspection Service, U.S. Department of Agriculture
ARS	Agricultural Research Service, U.S. Department of Agriculture

B

BA	Biological assessment
Beneficial Organism	Any organism directly or indirectly advantageous to plants or plant products, including biological control agents
Biological Control Agent	Any enemy, antagonist, or competitor used to control a plant pest or noxious weed; synonymous with Biological Control Organism
Butterfly House	An enclosure for public or private display of live domestic or exotic species of Lepidoptera (butterflies and moths)

C

CAFÉ	Computer Assisted Facility Evaluation
CBP	Customs and Border Protection, U.S. Department of Homeland Security
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
Commodity	A type of plant, plant product, or other article being moved for trade or other purpose
Containment	Application of phytosanitary measures in and around an infested area to prevent spread of a pest
Continued Curation	Permit for extension of contained holding of an organism under certain conditions for work or research
Control (of a pest)	Suppression, containment, or eradication of a pest populations

Country of Origin	Country where regulated articles were first exposed to contamination by pests or pathogens
Cumulative Impact or Effects	". . . the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions" (40 CFR § 1508.7)

D

Dissemination Potential	Ability of an organism to spread from the point of introduction or point of origin
Distribution	The frequency of numbers of organisms by location over the range within which those organisms occur

E

Ecosystem	A functioning natural unit including the biological species present, the physical environment (soil, water, air), and relationships among the components present
EIS	Environmental impact statement
Emergence	The exit of an adult insect from its pupa or cocoon
Entomopath-ogenic	A micro-organism that poses risk of lethal or other survival consequences to a host insect
Entomophagous	An organism that feeds upon a host insect
EO	Executive order
EPA	U.S. Environmental Protection Agency
ePermits	An electronic system designed to provide a secure way for stakeholders to apply for and receive permits as well as provide a means for Federal and State agencies to verify the authenticity and accuracy of permits
Eradication	Application of phytosanitary measures to eliminate a pest from an area
ESA	Endangered Species Act
Established	Population of an organism that will perpetuate for the foreseeable future
Establishment	Perpetuation, for the foreseeable future, of a pest within an area of entry

F

Facultative Hyperparasitoid — A parasitic organism which feeds upon the parasite of another organism (hyperparasite) or upon a nonparasitic host (primary parasitoid)

Field — A plot of land with defined boundaries within a place of production on which a commodity is grown

FONSI — Finding of no significant impact

FWS — Fish and Wildlife Service, U.S. Department of Interior

H

Habitat — Part of an ecosystem with conditions in which an organism naturally occurs or can establish

Hatching — The eclosion of organisms from their eggs

Host Pest List — A list of pests that infest a plant species, globally or in an area

Host Range — Species capable, under natural conditions, of sustaining a specific pest or other organism

Hyperparasitism — Ecological condition in which a parasitic organism feeds upon the parasite of another organism

I

Import Permit — Official document authorizing importation of a commodity in accordance with specified phytosanitary import requirements

Indigenous — Population of an organism of local origin to a given area

Infestation (of a commodity) — Presence in a commodity of a living pest of the plant or plant product of concern

Inspection — Official visual examination of plants, plant products, or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations.

Inspector — Person authorized by a National Plant Protection Organization to fulfill its functions.

Integrated Pest Management	An approach to pest control that involves consideration and application of all practical chemical and nonchemical methods.
Intended Use	Declared purpose for which plants, plant products, or other regulated articles are imported, produced or used.
Introduction	The entry of an organism into the environment.
Inundative Release	The release of large numbers of mass-produced biological control agents or beneficial organisms with the expectation of achieving a rapid effect.
IPM	See Integrated Pest Management
IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary Measures as agreed to under the International Plant Protection Convention

L

Legislative	Any act, law, regulation, guideline, or other administrative order promulgated by a government.

M

Mitigation	Measures taken to avoid or reduce adverse impacts on the environment; or, measures taken to avoid or reduce the likelihood of pest presence or survival in a commodity.
Mollusks	Any animals classified to be within the phylum Molluska, especially snails and slugs for permitting reviews.
Monitoring	An official ongoing process to verify phytosanitary conditions.
Monophagous	Feeding on a single kind of host species.
Movement	The authorized importation, interstate transport, and intrastate transport of plant pests under permit conditions for specific purposes.

N

	The authorized importation, interstate transport, and intrastate transport of plant pests under permit conditions for specific purposes.

Native	An organism whose origin is from the prescribed location.
Natural Enemy	An organism which lives at the expense of another organism in its area of origin and which may help to limit the size of that organism. This includes parasitoids, parasites, predators, phytophagous organisms, and pathogens.
NEPA	National Environmental Policy Act of 1969
Nonindigenous	Population of an organism of origin outside of a given area.
Nonquarantine Pest	An undesirable organism not officially controlled but of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed.
Noxious Weed	Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.
Obligate Primary Parasitoid	A parasitic organism which usually kills its host before the host produces offspring.
Occurrence	The presence in an area of a pest officially recognized to be indigenous or introduced and not officially reported to have been eradicated.
Official Control	The active enforcement of mandatory phytosanitary regulations and the application of mandatory phytosanitary procedures with the objective of eradication or containment of quarantine pests or for the management of regulated nonquarantine pests.
Organism	Any biotic entity capable of reproduction or replication in its naturally occurring state.
Outbreak	A recently detected population, including an incursion, or a sudden significant increase of an established pest population in an area.

P

Packaging	Material used in supporting, protecting, enclosing, or carrying a commodity.
Parasite	An organism that lives on or in a larger organism, feeding upon it.
Parasitoid	An insect parasitic only in its immature stages, killing its host in the process of its development, and free living in its adult stage.

Pathogen	Micro-organism capable of causing disease.
Pathway (Pest)	Any means that allows the entry or spread of a pest.
Pest	Any species, strain, or biotype of plant, animal, or pathogenic agent injurious to plants or plant products.
Pest Risk (Quarantine Pests)	The probability of introduction and spread of a pest, and the magnitude of the associated potential economic consequences.
Phytophagous	An organism that feeds upon plant species.
Phytosanitary Measures	Any legislation, regulation, or official procedure having the purpose to prevent the introduction and/or spread of pests.
Plant Pest	"Any living stage of any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts of parasitic plants, noxious weeds, viruses, or any organism similar to or allied with any of the foregoing, or any infectious substances, which can injure or cause disease or damage in any plants, parts of plants, or any products of plants" (7 CFR 319.40–1).
Polyphagus	Feeding on more than one kind of host species.
PPA	Plant Protection Act (Title IV of Pub.L. 106-224).
PPB	Pest Permitting Branch of PPQ; unit responsible for the review and issuance of permits for movement of plant pests and soil.
PPQ	Plant Protection and Quarantine, Animal and Plant Health Inspection Service, United States Department of Agriculture.
Predator	A natural enemy that preys and feeds on other animal organisms, more than one of which is killed during its lifetime.

Q

Quarantine	Official confinement of regulated articles for observation and research or for further inspection, testing, and/or treatment.
Quarantine Pest	An undesirable organism, officially controlled and of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed.

R

Range — The geographic area over which an organism occurs.

Regulated Article — Any plant, plant product, storage place, packaging, conveyance, container, soil and any organism, object or material capable of harboring or spreading pests, deemed to require phytosanitary measures.

Regulated Nonquarantine Pest — A nonquarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is, therefore, regulated within the territory of the importing contracting party.

Regulated Pest — A quarantine pest and/or a regulated nonquarantine pest.

Release — The movement of a regulated organism to a destination where it is intentionally or accidentally liberated into the environment.

RSPM — Regional Standards for Phytosanitary Measures as agreed to under the North American Plant Protection Organization.

S

Spread — The natural or human-mediated movement of a regulated organism to environments conducive to ongoing survival in those locations.

SPS — Sanitary and phytosanitary regulations/standards.

Stenophagous — Feeding on a single or limited kind of host species.

Sterile Insect — An insect that, as a result of a specific treatment or an inherent genetic condition, is unable to reproduce.

Sterile Insect Technique — Method of pest control using area-wide inundative release of sterile insects to reduce reproduction in a field population of the same species.

Suppression — The application of phytosanitary measures in an infested area to reduce pest populations.

T

TAG — Technical Advisory Group for Biological Control Agents of Weeds.

Treatment — Official procedure for the killing, inactivation, or removal of pests, or for rendering pests infertile or devitalized.

U

USDA — United States Department of Agriculture

V

Vector — An organism that is capable of carrying and spreading a disease or pest.

W

Wood Packaging Material — Wood or wood products (including pallets and dunnage) used in supporting, protecting, or carrying a commodity.

Appendix G. Response to Comments

Comment 1 – A commenter recommended removing the following language on page 51 of the draft EIS: "Similarly, if an organism was analyzed during the development of prior products, then subsequent use within new mixtures is not likely to trigger additional APHIS review or a new permit."

Response: APHIS removed this sentence.

Comment 2 – A commenter recommended deleting the following sentence on page 50 of the draft EIS: "In addition to EPA registered products, non-registered microbial pesticides that are transferred, sold, or distributed in accordance with 40 CFR 152.30 will not be regulated under 7 CFR Part 330. However, many microbial species, e.g. *Bacillus subtilis*, have both pesticidal and non-pesticidal strains and some strains have both pesticidal and non-pesticidal attributes. Those not overseen by EPA as pesticides via pesticide registration, pesticide experimental use permit, or via 40 CFR 152.30 are therefore not exempt from 7 CFR Part 330 on the basis that they are adequately regulated by EPA."

Response: APHIS added the sentence to the final EIS.

Comment 3 – A commenter recommended that the final EIS strengthen the discussion of Executive Order (EO) 13175, Consultation and Coordination with Indian Tribal Governments by providing support for the conclusion that consultation with tribes is not indicated. If tribal consultation issues will be addressed at the permitting stage, we recommend that be included in the discussion.

Response: APHIS added a discussion of this EO in the final EIS.

Comment 4 – A commenter recommended that APHIS strengthen the discussion of EO 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (February 11, 1994) with respect to the following:

• the final EIS should discuss the relevance of future, permit-specific NEPA for purposes of identifying and addressing any EJ concerns that may arise.

• the final EIS discussion reference, as appropriate, tools available to assist in screening for impacts to low-income and minority populations within or near areas proposed for plant movement at the permitting stage, including EPA's EJSCREEN. Use of these tools would strengthen APHIS 's analysis to help support the statement in the DEIS, Section e. Executive Order 13045--Protection of Children from Environmental Health Risks and Safety Risks, page 95 " Both EO 12898 and EO 13045 call for special environmental reviews in certain circumstances. No circumstance that would trigger the need for special environmental reviews is involved in implementing the preferred action considered in this document. No disproportionate adverse effect is anticipated to any minority, low-income population, or particular subgroup of the United States population."

• the final EIS should discuss the importance of outreach to EJ populations at the permitting stage, which can include various forms of media such as radio, television, newspapers, and social media.

Additionally, more direct stakeholder engagement at local libraries, food establishments as well as school and religious institutions may be appropriate.

• APHIS could also consider strategies outlined in the "Promising Practices for EJ Methodologies in NEPA Reviews" report when considering EJ at the permitting stage.

The following language was added to the final EIS:

Both EO 12898 and EO 13045 call for special environmental reviews in certain circumstances. In particular, when first time environmental releases of biological control agents or other organisms are proposed, special environmental reviews may be necessary. APHIS can use EJSCREEN (available at https://toolkit.climate.gov/tool/ejscreen-environmental-justice-screening-and-mapping-tool), EPA's environmental screening and mapping tool that provides demographic and environmental information for a geographic area. APHIS can reach out to minority and low income populations when necessary by using radio, television, newspapers, the APHIS stakeholder registry, and social media, as well as other techniques outlined in "Promising Practices for EJ Methodologies in NEPA Reviews" (FIWGEJ and NEPA Committee, 2016).

This sentence was removed from the final EIS:

No circumstance that would trigger the need for special environmental reviews is involved in implementing the preferred action considered in this document. No disproportionate adverse effect is anticipated to any minority, low-income population, or particular subgroup of the United States population."

Appendix H. Index

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